EFFECT OF CRYOTHERAPY ON ARTERIOVENOUS FISTULA PUNCTURE RELATED PAIN AMONG PATIENTS UNDERGOING HEMODIALYSIS AT SELECTED HOSPITAL, COIMBATORE.

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The Tamilnadu Dr. M.G.R Medical University,

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In Partial Fulfillment of the Requirement for the

Award of the Degree of

MASTER OF SCIENCE IN NURSING

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This is to certify that the dissertation entitled **"Effect of Cryotherapy on Arteriovenous Fistula Puncture Related Pain among Patients Undergoing Hemodialysis at Selected Hospital, Coimbatore."** is a bonafide work done by **J. BERIN SHEEBA, College of Nursing, Sri Ramakrishna Institute of Paramedical Sciences** in partial fulfillment of the University rules and regulations for award of **M.Sc. Nursing Degree** under my guidance and supervision during the academic year **2018.**

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EFFECT OF CRYOTHERAPY ON ARTERIOVENOUS FISTULA PUNCTURE RELATED PAIN AMONG PATIENTS UNDERGOING HEMODIALYSIS AT SELECTED HOSPITAL, COIMBATORE

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ABSTRACT

Pain is not just a physical sensation. It is influenced by attitude, beliefs, personality and social factors and can affect emotional and mental wellbeing. Pain during arteriovenous fistula (AVF) cannulation remains a common problem in hemodialysis patients that leads to noncompliance to lifetime maintenance hemodialysis. Cryotherapy is the non-pharmacological therapy which helps to reduce the pain among patients undergoing hemodialysis. The aim of the study was to identify the effect of cryotherapy on arteriovenous fistula puncture related pain among patients undergoing hemodialysis. Repeated measures cross over design was adopted in this study. A total of 38 patients undergoing hemodialysis through AVF were selected in hemodialysis unit at Sri Ramakrishna hospital, Coimbatore. Among 38 samples, 19 patients were allotted in Group I who were given routine care first alternated by cryotherapy on subsequent visits and other 19 patients were allotted to Group II who were given cryotherapy first alternated by routine care for a period of two weeks. Objective pain assessment was done using Modified Abbey pain scale during AVF puncture and subjective pain assessment was done using Numerical Pain Rating scale after AVF puncture. Finding revealed that the mean score of objective pain during routine care and cryotherapy was 4.03 and 1.83 with standard deviation was 1.31 and 0.84 among patients in Group I. Whereas, the mean score of objective pain during cryotherapy and routine care was 1.76 and 3.82 with standard deviation was 0.64 and 0.88 among patients in Group II. The mean score of subjective pain after routine care and cryotherapy was 6.07 and 2.04 with standard deviation was 1.76 and 1.58 among patient in Group I. Whereas, the mean score of subjective pain after cryotherapy

and routine care was 2.08 and 6 with standard deviation was 0.89 and 0.94 among patients in Group II. There was a significant difference in the arteriovenous fistula puncture related objective type pain between the interventions in Group I and II ($t = 5.8$ and 7.9, $p<0.001$). There was a significant difference in the arteriovenous fistula puncture related subjective type pain between the interventions in Group I and II ($t = 6.95$ and 12.65, $p<0.001$). Correlation between Modified Abbey objective pain scale and Numerical subjective pain rating scale among recipients of cryotherapy was 0.6. The result showed that the subjective pain score perceived by the patients and the objective pain score observed by the researcher was positively correlated. Hence, it was concluded that cryotherapy is an effective intervention in reducing the level of arteriovenous fistula puncture related pain among patients undergoing hemodialysis.

INTRODUCTION

“It is health that is real wealth and not pieces of gold and silver”

-Mahatma Gandhi

Healthy lifestyles are a key component of optimal wellness in young adult and essential tool for minimizing the incidence and severity of chronic illness and their complications and an effective strategy for controlling rising health care cost. It is the vehicle for attaining most of the goal of health promotion and disease prevention.

Increasing society’s attention towards healthy behaviors remains a challenge. The cost of chronic illness management continues to drive the cost of health care afford. Because of modernization and industrialization, an individual moves towards health care system. (Phipps, 2009).

The kidneys are powerful "chemical factories" that removes waste and drugs from the body, balance the body's fluids, release hormones that maintains blood pressure and stimulate red blood cell production, filtering and returning to the bloodstream about 2 litres of fluid every 24 hours. (Ryan, 2013).

In renal failure, the kidney is unable to filter metabolic waste from the blood. The symptoms of renal failure depend on its severity, whether it is acute or chronic. The signs of renal failure start within a few hours to few days or to weeks or months or years. (Medi Resource Clinical Team, 2017).

Chronic renal failure (CRF) refers to many clinical abnormalities that progressively worsen as kidney's function declines. A glomerular filtration rate (GFR) persistently below 60 mL/minute/1.73 m^2, which is below the level of kidney function. In CRF, the damage is rarely repaired, so loss of function persists. The chronic loss of kidney function generates even more kidney damage and more severe clinical abnormalities. As a result, CRF progressively worsens even if the disorder that caused it becomes inactive. (Mitch, 2012).

CRF is an enormous public health issue, the tide of which continues to inexorably rise. In 2015, Global Burden of Disease Study revealed that kidney disease was the 12th most common cause of death, accounting for 1.1 million deaths worldwide. Overall CRF mortality has increased by 31.7% over the last 10 years, making it one of the fastest rising major causes of death. This is in stark contrast to other non-communicable diseases, for example cardiovascular disease and chronic obstructive pulmonary disease, where global years lost of life fell during the same time period (−10.2% and −3.0%, respectively). (Neuen, Chadban, Demaio, Johnson and Perkovic, 2017).

In the United States, 30 million people are estimated to have CRF. In 2014, 118,000 people started treatment for ESRD and 662,000 are living on chronic dialysis or with a kidney transplant. Men of 64% are more likely than women to develop ESRD. The study reported that main causes of ESRD are diabetes and hypertension in age group more than 18 years. Likewise, in adolescents group the cause is glomerulonephritis. (National Chronic Kidney Disease Fact Sheet, 2017).

National Center for Chronic Disease Prevention and Health Promotion estimated that Information consolidated from 150 countries worldwide showed a number of patients being treated globally for ESRD of 3,010,000 at the end of 2012 and the ratio is growing faster than the world population (growth rate: 7%). At the end of 2012, hemodialysis was most common treatment modality, with approximately 2,106,000 (89%) patients and around 252,000 (11%) patients are undergoing peritoneal dialysis. In Europe, the average growth rate of the dialysis patient population between 2011 and 2012 was about 2%. The last report of the Italian Registry of Dialysis and Transplant (RIDT 2010) depicted a prevalence of hemodialysis and peritoneal dialysis of 788 patients per million population (PMP) and an incidence of 162/PMP (42,488 patients in hemodialysis, including 8,638 incident patients). In Piedmont, the prevalence of dialysis is lower than in Italy and has been stable over the last 9 years. The incidence has varied between 150 and 165 PMP in the last years. (Roggeri, Alessandro Roggeri, and Salomone, 2014).

In India, one in every ten adults is suffering from chronic renal failure. 17% of urban Indians are suffered with CRF. It is necessary to create more awareness about the symptoms and encourage those at higher risk. (The Economics Times, June 8, 2017). Diabetes is the major cause of chronic renal failure and found in 31.2 - 41% of patients in India. The projected numbers of deaths due to chronic renal failure are around 5.21 million in 2008 and are expected rise up to 7.63 million in 2020. (Patidar, 2015).

Hemodialysis is one of three renal replacement therapies with the arteriovenous fistula being the gold standard for vascular access in hemodialysis patients. Pain inflicted by the insertion of large cannula into the arteriovenous fistula is a significant cause of concern for both children and adults on regular hemodialysis. Local anesthesia is not frequently used for AV fistula puncture related pain due to concerns of vasoconstriction, burning sensation, scarring and infection. (Sabitha,et al 2008).

Patients undergoing hemodialysis are exposed to stress and pain due to approximately 300 punctures per year they receive for their arteriovenous fistula. Alleviation of the pain can improve acceptance of the procedure and quality of life among the patients. Administration of cryotherapy as a safe method with low side effects is suggested for pain control among patients with hemodialysis. (Aghajanloo, Ghafourifard, Haririan, and Gheydari, 2016).

Cryotherapy is used for treatment of pain by slowing nerve conduction rate and blocking nerve impulses through lowering the temperature over the affected area. It also relaxes muscles, decrease capillary permeability by vasoconstriction and slow cellular metabolism. It can be applied topically, percutaneously or surgically. The cold application can be delivered by cold packs, ice gel, ice massage or spray. (Fareed, Abd El-Hay and El-Shikh, 2014).

Cryotherapy has been accepted for decades as an effective, inexpensive and non-pharmacological intervention for pain management. (Algafly and George, 2007). It is widely believed that the therapeutic application of cryotherapy leads to a reduction in pain and swelling. Cryotherapy is effective in reducing subjective type of pain and objective behavioral response scores of arteriovenous fistula puncture related pain. (Lijiya and Diana, 2015).

1.1 Need for the study

Chronic Renal Failure is a term that encompasses all degrees of decreased renal function, from damaged–at risk through mild, moderate, and severe chronic renal failure. It is a worldwide public health problem.

Chronic renal failure is more prevalent in the elderly population. However, while younger patients with chronic renal failure typically experience progressive loss of renal function, 30% of patients over 65 years of age with chronic renal failure have stable disease. Chronic renal failure is associated with an increased risk of cardiovascular disease and chronic renal failure. (Arora, 2017).

Chronic renal failure is a global health burden with a high economic cost to health systems and is an independent risk factor for cardiovascular disease. Chronic renal failure has a high global prevalence rate between 11 to 13% with the majority stage 3. In western countries, diabetes and hypertension account for over 2/3rd of the cases of chronic renal failure. (Hill et al., 2016).

Majority of the Indian population is suffering from chronic disease such as diabetes or hypertension. Because of negligence or unawareness or due to the poor control towards health and these contribute to further more disease such as renal failure. (Abraham and Ramachandran, 2012). In India, it is estimated that about 1 lakh persons suffer from ESRD each year. Maintenance dialysis therapy is the commonest mode of Renal Replacement Therapy and demand for this service is increasing progressively. (Reddenna, Basha, Reddy, 2014).

Prevalence of the disease are varies by region in India. Urban areas have much higher rates than rural areas and Northern India has higher rates than Southern India. For example, New Delhi had a CKD rate of more than 40 percent

in 2013, while Mysore and Bangalore had rates of about 4 percent. (India's Dialysis Market, 2013). An Indian population-based study determined the crude and age-adjusted ESRD incidence rates at 151 and 232 per million populations, respectively. It is estimated that there are about 55,000 patients on dialysis in India, and the dialysis population is growing at the rate of 10–20% annually. (Jha, 2013).

Pain intensity in chronic renal patients under hemodialysis during the arteriovenous fistula cannulation. During cannulation, the pain reported was moderate in 58.5% of patients, intense in 30% and mild in 11.5%. There was no association between the occurrence of pain in relation to gender, shift and time of hemodialysis. The study points out to the need for pre-cannulation analgesia to improve comfort during the procedure. (Silva, Rigon, Dalazen, Bissoloti, Rabelo-Silva, 2016).

Pain perception during fistula needle insertion remains an uncontrolled concern for hemodialysis patients and it considered as one of the major causes of treatment rejection among ESRD patients. AVF puncture-related pain is a common complication in patients on hemodialysis. Pain management in the scope of all health professionals especially nurses and it is an important component of comprehensive nursing care. Nursing effort should be made to assess and mange acute pain inflicted by insertion of needle in arteriovenous fistula among hemodialysis patients. (Fareed, Abd El-Hay and El-Shikh, 2014).

Pain management starts with conservative options such as pharmacological and non-pharmacological interventions. Non-pharmacologic interventions are behavioral- cognitive strategies such as distraction, relaxation, biofeedback, thought stopping, positive self-talk, guided imagery and biophysical interventions such as massage, pressure, transcutaneous electrical nerve stimulation (TENS) and heat and cold application. (Hassan, Darwish, El-Samman and Fadel, 2012).

Cryotherapy (cold application) as a cutaneous stimulation technique is an inexpensive nursing intervention that is advocated to minimize pain in patients. (Golda, et al 2016). The cutaneous stimulation is best explained by the gate control theory in minimizing pain. It can be clubbed with acupressure to the large intestine energy meridian to increase its effectiveness. The large intestine meridian is an acupressure point located on the back side of the hand between the thumb and index finger which is used dominantly to relive pain of shoulder, arm, and rigidity of the neck, scapula and eye disease. The most effective site of cutaneous stimulation is contralateral to the pain. (Fareed, Abd El-Hay and El-Shikh, 2014).

Nurses as advocates for adults, are committed to minimize the emotional and physical impacts of painful procedures. Providing pain relief is considered a most basic human right and it is the obligation of the nurse to utilize best way to deal with pain control. Experience with patients on hemodialysis during the clinical posting initiated the researcher interest to help the patient with their pain and they expressed their symptoms and problems they face in daily life. Among all the symptoms pain is one of their major problem. Hence there are more

number of people experiencing pain during arteriovenous fistula puncture as a lifelong process. For this reason the researcher had selected this study to help them to improve their wellness by lowering level of pain.

1.2 Statement of the problem

Effect of Cryotherapy on Arteriovenous Fistula Puncture related Pain among Patients undergoing Hemodialysis at a Selected Hospital, Coimbatore.

1.3 Objectives

1.3.1 To assess the level of arteriovenous fistula puncture related pain among patients undergoing hemodialysis after cryotherapy and routine care.

1.3.2 To evaluate the effect of cryotherapy on arteriovenous fistula puncture related pain among patients undergoing hemodialysis.

1.3.3 To correlate between the arteriovenous fistula puncture related pain observed using Modified Abbey pain scale and Numerical Pain Rating scale among patients undergoing hemodialysis after cryotherapy and routine care.

1.4 Operational Definition

1.4.1 Effect

It is an extent to which cryotherapy causes change in the level of arteriovenous fistula puncture related pain among patients undergoing hemodialysis. The objective level of pain was assessed by Modified Abbey pain scale and subjective level of pain was assessed by Numerical Pain Rating scale.

1.4.2 Cryotherapy

It is the application of ice gel pack on the web between thumb and index finger of the opposite hand (contralateral) 10minutes before the arteriovenous fistula puncture and continued until arteriovenous puncture (approximately 2 minutes).

1.4.3 Arteriovenous fistula

It is the gold standard vascular access used to access the blood for hemodialysis treatment for those with chronic renal failure. It is created by connecting a vein to an artery using a soft plastic tube.

1.4.4 Pain

Pain is an unpleasant sensory and emotional experience associated with procedure of arteriovenous fistula puncture. Objective type of pain is assessed by Modified Abbey pain scale and Subjective type of pain is assessed by Numerical Pain Rating scale.

1.4.5 Patient undergoing hemodialysis

It is the type of patients who are undergoing two or more cycles of hemodialysis in a week through arteriovenous fistula.

1.5 Hypothesis

$H_0$1: There is no significant difference in the arteriovenous fistula puncture related pain between interventions.

$H_0$2: There is no significant difference in the arteriovenous fistula puncture related pain between groups.

$H_0$3: There is no significant correlation between the Modified Abbey pain scale and Numerical Pain Rating scale between groups.

1.6 Conceptual Framework

The conceptual framework is a "sets the stage" for the presentation of the particular research question that initiates the investigation being reported based on the problem statement. The problem statement of a thesis presents the context and the issues that caused the researcher to conduct this study.

A conceptual framework is made up of concepts, which are the mental images of the phenomenon and it offers framework of prepositions for conducting research. These concepts are connected together to express the relationships between them. A model is used to denote symbolic representation of the concepts or ideas.

Conceptual framework of this study was based on the helping art in clinical nursing theory by Ernestine Widen Bach in 1964. The theory focused on three concepts such as identification, ministration and validation. According to Wieden Bach, nursing practice consist of identifying a client's need for help, caring the needed help and validating the needed help.

Identification

Identification involves observing a client as an individual with unique experiences and understanding the client's perception of the condition. In this study, identification refers to the selection of patients undergoing hemodialysis through AV fistula by using demographic variables.

Ministration

Ministration refers to providing of needed help. In this study, the ministration refers to administering cryotherapy and routine care for patients with arteriovenous fistula puncture related pain among undergoing hemodialysis.

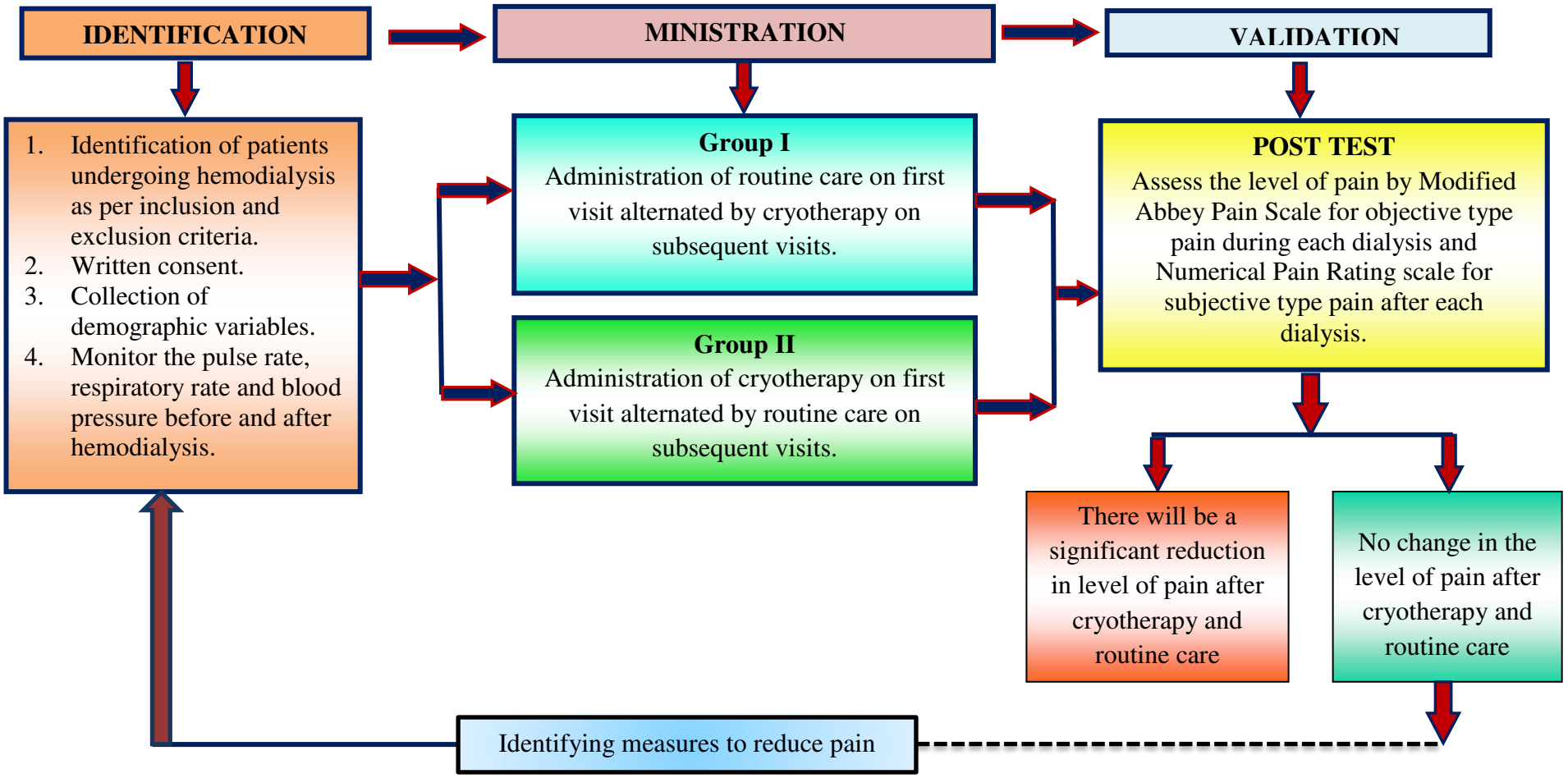
Validation

Validation is expressions of patient satisfaction as the need for help is resolved. Here the validation refers to assessment level of arteriovenous fistula puncture related pain after administration of cryotherapy and routine care by using subjective type of pain is assessed by Numerical Pain rating scale and objective type of pain is assessed by Modified Abbey pain scale.

Feedback

It refers to the process by which information is received at each stage of the system and it is given based on evaluation. In this study, feedback refers to improvement level of arteriovenous fistula puncture related pain among patients undergoing hemodialysis.

Table 1.1 Conceptual framework on Modified Widen Bach's helping art of Clinical Nursing Theory (1964)



(Source: Wesley, 1964)

1.7 Projected Outcome of the Study

Application of cryotherapy will reduce the arteriovenous fistula puncture related pain among patients undergoing hemodialysis.

LITERATURE REVIEW

Review of literature is an important stage in the development of a research project. It helps the researcher to develop a deeper insight into the problem and gain information on the problem and on what has been done before it provides basis for future investigation justified the need for replication, through light on the feasibility of the study to another with a hope to establish a comprehensive body of scientific knowledge in professional discipline from which, valid and pertinent theories may be developed.

The literature gathered for this study was discussed under the following sections.

2.1 Literature related to Hemodialysis.

2.2 Literature related to arteriovenous fistula puncture related pain.

2.3 Literature related to cryotherapy.

2.4 Literature related to cryotherapy and arteriovenous fistula puncture related pain.

2.1 Literature Related to Hemodialysis

DujićN (2016) conducted a study of quality of life of dialysis patients. A meta-analysis was used MEDLINE and EBSCO databases to search during 2005-2016 period. According to the survey, quality of life in dialysis patients is significantly lower as compared to general population. Renal transplantation is better HRQOL as compared to dialysis, since there is no significant difference in HRQOL between patients on hemodialysis and those on peritoneal dialysis. Good clinical practice in the treatment of dialysis patients is based on individual approach and improving the quality of life, which is collaboration of family doctors and consultant nephrologists is necessary.

Abraham and Ramachandran (2012) performed a study on estimation of quality of life in hemodialysis patients and to evaluate the variables affecting the QOL. A longitudinal and comparative study was conducted for one year (March 2011 to February 2012) in the nephrology department of a tertiary care hospital. Around 81 samples were selected, in that 35 patients considered as test group and others considered as control group (*n*=46). Patients were interviewed and the demographic data and the details of comorbid conditions were collected. Patient counselling was provided to the test group patients regarding their disease, diet, exercise, lifestyle modification, use of medication and the importance of regular dialysis through the verbal and written materials. QOL was determined by the generic instrument WHO quality of life questionnaire comprised of 26 items, which measures four domains: physical, psychological, social and environmental domain. The study showed that improve the functioning ability of these patients by patient counselling. Patient counselling helped to gain benefits in terms of improvement in QOL and delayed progression of renal failure.

Janssen et al (2015) conducted a study to preferences of patients undergoing hemodialysis in Germany. It was to rate the relative importance of different outcomes for hemodialysis patients and analyze whether the relative importance differed among 4,518 hemodialysis patients were included and structured questionnaire was distributed. Also assessed the relative importance of 23 outcomes as rated on a discrete visual analog scale. The three most important outcomes were safety of treatment, health-related quality of life, and satisfaction with care and other important outcomes were hospital stays, accompanying symptoms, hemodialysis duration, and the improvement or preservation of a good

emotional state. Age, profession and education had the strongest influence on relevant differences of preferences for outcomes and no relevant influence of sex or comorbidity was observed. Outcomes concerning the delivery or provision of care and aspects influencing quality of life are rated by patients to be at least as important as clinical outcomes. Most of the outcomes judged to be important by the patients are not regularly considered in research, evaluation studies, or quality programs.

Xhulia et al (2016) conducted a study to describe the needs of hemodialysis patients. Data collection with interview method was adopted among 141 patients undergoing hemodialysis by using questionnaires method. The study shows that patients evaluated as fairly important all six categories of patients needs, with similar results in both sex. Age was found to be significantly associated with the need for support and guidance the need to be informed and the need to meet the emotional and physical needs (p=0.023, p=0.012, p=0.028 respectively). Education level was found to be significantly associated with all patients needs with the exception of the need to trust the medical and nursing staff (p=<0.05). Place of residence was statistically significantly associated with 'the need for support and guidance (p=0.029). Furthermore, difficulties in relations with family members was found to be statistically significantly associated with the need for support, the need for communication and individualization of care (p=0.014, p=0.040, p=0.041). After multivariate analysis, however, it was shown that the only independent factor affecting the need for support and guidance the need for individualized care and the need to meet the emotional and physical needs was if the patients reported themselves as anxious or not (p=0,024, p=0,012

and p=0,004, respectively). In particular, patients who considered themselves anxious had 1.38, 1.5 and 1.6 points respectively higher score in the evaluation of the importance of needs compared to patients who did not consider themselves anxious.

Agarwal (2014) performed a study on magnitude and issue involved in chronic renal failure in India. The approximate prevalence of CKD is 800 per million population (pmp) and incidence of ESRD is 150-200 pmp. The commonest cause of CKD is diabetic nephropathy. India currently has around 1200 nephrologist, 1500 hemodialysis units with 10000 dialysis stations and 6000 patients on CAPD. India has around 230 renal transplant centers; 80% in private set-up. Nearly 6000 renal transplants are done annually, cadaver being <10%. Thus, nearly 18000-20000 patients (10% of new ESRD) get renal replacement therapy. Cost of hemodialysis varies between 1000- 3000 rupees with an additional cost of erythropoietin being 5000 rupees /months. Cost of CAPD using "Y" set with three exchanges/week is around 25000/month. Cost of transplant procedure is rupees 30000 (Govt. sector) to Rs. 3.0 Lakh (Pvt. sector) with cost of immunosuppression using Tacrolimus, steroid and Mycophenolate is Rs. 15000-400/month. The life expectancy of 63 years being increasing further, with time magnitude of CKD is going to increase.

Qin, Jia and Liu (2016) conducted a study on nursing strategies for patients with chronic renal failure undergoing maintenance hemodialysis. Ninety-two patients with chronic renal failure undergoing maintenance hemodialysis (MHD) between Jan 2014 and Jan 2015 were included in the study

(all undergoing AVF, dialysis for 2–3 sessions per week, 4–5 h per session) and randomly divided into control group and observation group. Patients in control group were given standard nursing care and patients in observation group were given professional nursing of internal fistula. The complication rate and dysfunction rate during internal fistula perioperative period, fistula usage time and effect on life quality of patients of these two groups were compared (during 18-month follow-up). The complication rate and dysfunction rate during internal fistula perioperative period of the observation group were significantly lower than that of the control group, and the difference was statistically significant ($P<0.05$). The median time of internal fistula usage was significantly prolonged, and the health index, emotion index and psychology index quality-of-life in the observation group were significantly higher than that of the control group ($P<0.05$).

Roggeri, Roggeri and Salomone (2014) performed a study on chronic kidney disease evolution of healthcare costs and resource consumption from pre dialysis to dialysis in piedmont region, Italy. A retrospective study was adopted with patients undergoing at least one dialysis for CKD in the period of June 1, 2010 - May 31, 2011. Two subpopulations were evaluated. Patients incidents of dialysis observed for the 12 months preceding dialysis entrance (PreD) and "established" dialysis patients (at least 120 dialyses/year) observed for 12 months (EstD). Overall, 1,059 PreD and 2,018 EstD patients were selected. The average yearly cost per PreD patient accounted for 11,123€ ± 15,095€ (75% hospitalizations, 17% drugs, and 8% diagnostic/therapeutic procedures). The average yearly cost per estimated patient accounted for 53,764€ ± 14,685€ (59% dialysis, 21% diagnostic/therapeutic procedures, 13% hospitalizations

and 6.7% drugs). Among estimated population, hemodialysis patients cost 56,049€ ± 13,473€ per year, whereas peritoneal dialysis patients cost 34,978€ ± 10,847€ per year. The significant difference in expenditure between pre dialysis and dialysis suggests that prevention, early diagnosis, and the consequent possible delay of dialysis entrance could lead to important savings for healthcare services, as well as a better global health status for patients.

Dare et al (2017) states about renal failure deaths and their risk factors in India between 2001–13. The cross-sectional study of population based data was conducted by two trained physicians independently and identify the underlying causes to 150 018 deaths at ages 15–69 years from a nationally-representative mortality survey in India for 2001–03 and 2010–13, using the International Classification of Diseases, 10th version (ICD-10). The study result showed that in 2001–03, 2·1% of total deaths among 15–69 year were from renal failure. By 2010–13, the proportion of deaths from renal failure had risen to 2·9% of total deaths and corresponding to 136 000 renal failure deaths (range 108 000–150 000) of 4 688 000 total deaths nationally in 2015. Age-standardized renal death rates were highest in the southern and eastern states, particularly among adults aged 45–69 years in 2010–13. Diabetes, hypertension and cardiovascular disease were significantly associated with increased renal failure deaths, with diabetes the strongest predictor odds ratio (OR) *vs* control 9·2 (95% CI 6·7–12·7) in 2001–03, rising to 15·1 (12·6–18·1) in 2010–13. In the 2010–13 study population, the diabetes to non-diabetes OR was twice as large in adults born in the 1970s (25·5, 95% CI 17·6–37·1) as in those individuals born during or before the 1950s (11·7, 9·1–14·9). The result revealed that renal failure is a growing cause of premature death and poorly treated diabetes is the most probable reason for this increase.

2.2 Literature Related to Arteriovenous Fistula Puncture Related Pain

Kafkia, Julkunen, and Krepia (2014) conducted a study to assess pain levels of hemodialysis) patients and to report pain management techniques. A pilot study with interview method by using the Visual Analog Scales (VAS), the Wong-Baker Pain Scales (WBPS) and McGill Pain Questionnaire was adopted among 79 patients undergoing hemodialysis. Among the patients 69.72 ±12 were 45 years old, male (58.5%) and on HD for 35.5 ± 27.4 months. In the Wong Baker Scale, pain was rated as hurts little more (30.8%), (n=20) and in the VAS 30.8% (n=20) reported 6/10 the amount of pain experienced. Forty-six percent pinpointed internal pain in the legs. Pain experienced was characterized as sickening (70.8%), tiring (67.7%), burning (66.2%), rhythmic (86.2%), periodic (66.2%) and continuous (61.5%). The patients studied mainly manage pain either with warm towel/cloth (85.2% females and all male patients), with massage (84.2% and 88.9%, respectively) or painkillers (47.4% and 52.6%, respectively). In a correlation of gender and pain management techniques, statistical significance was found only with warm towel (p=0.038).

Silva, Rigon, Dalazen, Bissoloti, and Rabelo-Silva (2015) performed a study to evaluate pain during arteriovenous fistula cannulation in chronic renal patients on hemodialysis. A cross-sectional study conducted in a hemodialysis clinic in the second semester of 2014. Seventy individuals participated in the research and were assessed by the visual analogue scale. During cannulation, the pain reported was moderate in 58.5% of patients, intense in 30% and mild in 11.5%. There was no association between the occurrence of pain in relation to gender, shift and time of hemodialysis. The study points out to the need for pre-cannulation analgesia to improve comfort during the procedure.

Nagi, Multani and Arora (2016) performed a study on arteriovenous fistula for hemodialysis in patients suffering from chronic renal failure and assess the various complications which encountered while creating arteriovenous fistula and post operatively during the period when fistula matures. The study was comprised of 83 patients suffering from chronic renal failure and required arteriovenous fistula for carrying out hemodialysis. The study revealed that there was no major complications after creating arteriovenous fistula and it is imperative to do physical examination preoperatively to assess the vessel wall.

Figueiredo, Viegas, Monteiro and Poli-de-Figueiredo, (2008) conducted a study on pain perception with arteriovenous fistula cannulation. Repeated AVF punctures lead to a considerable degree of pain, due to the caliber and length of the bevel of fistula needles. The objective of this study was to measure the pain associated with AVF puncture with using analogue visual scale (AVS). Pain was considered mild during AVF puncture. The buttonhole technique caused a mean degree of pain of 2.4 (+/-1.7), compared to 3.1 (+/-2.3) using the conventional rope ladder technique. Although without reaching a statistically significant difference, diminished pain was associated with the buttonhole technique.

Kaza et al (2014) a study to attempted on pain during arteriovenous fistula (AVF) cannulation and purpose was to estimate prevalence, risk factors and take care of pain due to AVF cannulation to hemodialysis patients. Monocenter study was adopted September 1st to 30th, 2013 in the unit of hemodialysis of University Teaching Hospital Ibn Rochd of Casablanca. It included 92 hemodialysis patients with AVF dating of at least three months. Intensity of pain estimated by means of an analogue visual scale. The pain was estimated at every patient's during two

consecutive hemodialysis sessions just after the bipunction of AVF by means of needles of 16 gauge by the same nurse. The mean age was 43,76 ± 13,6 years with a parity of sex. Prevalence of pain was 60,9 % with a moderate intensity expressed in 63 % of cases. About 31,5 % had apprehension of puncture. The anesthetic cream was the only method used for pain take care and its rate of use was 3.6 %. The risk factors of the pain were: proximal situation of AVF (p=0.020), apprehension of puncture (p=0.037). In our hemodialysis center, pain during AVF cannulation remains a real problem both by its high prevalence and its lower take care.

2.3 Literature Related to Cryotherapy

Ramadan, El-Fouly, Sharaf and Ayoub (2016) conducted a study to assess the effect of cryotherapy on pain intensity among adult patients receiving intramuscular injections. Quasi–experimental time-series design was carried out in this study with hundred samples. Structured interview questionnaire was used to collect data include socio-demographic and health data, Universal pain assessment tool and Observation Checklist of nonverbal pain indicator (OCNPI). Results showed significant positive relation of pain scores before and after the intervention. The study concluded that there was a significant positive effect of cryotherapy on reducing IM injection pain (P value is 0.0001). The study was recommended that medical departments can apply cryotherapy technique to reduce needle puncture pain for IM injection in routine care.

Kadakia, Rozell, Butala, and Loprinzi (2016) attempted a study to supportive cryotherapy: a review from head to toe. A comprehensive search using PubMed, Ovid, Embase and MEDLINE(®) was completed. References of all cited articles also were reviewed. Data from the review were composed of articles

published between 1970 and May 2013. Available evidence suggests that regional hypothermia reduces the burden of chemotherapy-related oral mucositis, alopecia, ocular toxicity and onychosis. The major limitations of studies include the absence of blinded control groups and variable clinical end points. Regional hypothermia decreases the burden of these four chemotherapy-induced complications and is well tolerated.

Riley, et al (2016) conducted a study on assess the effects of oral cryotherapy for preventing oral mucositis in patients with cancer who are receiving treatment. Meta-analysis was reviewed from 1937 to 2015. Among 14 RCTs analyzing 1280 participants. The vast majority of participants did not receive radiotherapy to the head and neck, so this review primarily assesses prevention of chemotherapy-induced oral mucositis. 5 studies and 444 were analyzed. In a population where 728 per 1000 would develop oral mucositis, oral cryotherapy would reduce this to 444 (95% CI 379 to 524). Researcher confident that oral cryotherapy leads to large reductions in oral mucositis of all severities in adults receiving 5FU for solid cancers.

Algafly and George (2007) conducted a study on effect of cryotherapy on nerve conduction velocity, pain threshold and pain tolerance. Experimental design was adapted with convenience sample of 23 adult male sports players. All outcome measures were assessed at two sites served by the tibial nerve: one receiving cryotherapy and one not receiving cryotherapy. In the control ankle, NCV, PTH and PTO did not alter when reassessed. In the ankle receiving cryotherapy, NCV was significantly and progressively reduced as ankle skin temperature was reduced to 10°C by a cumulative total of 32.8% ($p<0.05$). Cryotherapy led to an increased PTH and PTO at both assessment sites

($p<0.05$). The changes in PTH (89% and 71%) and PTO (76% and 56%) were not different between the iced and non-iced sites. The data suggest that cryotherapy can increase PTH and PTO at the ankle and this was associated with a significant decrease in NCV. Reduced NCV at the ankle may be a mechanism by which cryotherapy achieves its clinical goals.

Shin, Park, and Choi (2012) performed a study on effects of nursing intervention on pain control during chemo port needle insertion. Non-equivalent control group design was adopted with 120 subjects. 90 subjects were included in the experimental group and 30 subjects were included in the control group. According to the results, the Hypothesis I was validated with the following results: subjective pain score: $F=26.76$, $p<0.0001$ and objective pain score: $F=17.00$, $p<.0001$. With this result, a post-hoc assessment was made through Duncan's Multiple Range Test. Based from the result, the pain scores (subjective and objective scores) were significantly lower than the scores derived from the control group.

Greenstein (2007) attempted a study on therapeutic efficacy of cold therapy after intraoral surgical procedures. The literature was searched for clinical trials that assessed the benefits of cryotherapy after oral surgical procedures. In addition, other studies were reviewed that evaluated the physiological responses to cold therapy. Study result shows that inhibit signs of inflammation, reduction of edema, diminished pain perception and achieve beneficial results with cryotherapy, skin temperature (normally 33 degrees C) needs to be reduced to 10 degrees C to 15 degrees C. Cold therapy usually decreased skin temperature 10 degrees C to 15 degrees C within

10 to 20 minutes. Seven studies published in English were found that addressed the use of cryotherapy after oral surgical procedures. Five investigations demonstrated no clinical benefits from cold therapy, and two studies indicated that cryotherapy reduced post-surgical edema and pain. Cryotherapy should be applied for 10 to 20 minutes followed by a rest period. The duration of therapy ranged from 2 to 72 hours. This study revealed that ice applied after surgical procedures may reduce swelling and discomfort.

Mahshidfar et al. (2016) conducted a study aimed to determine the effectiveness and safety of cryotherapy in patients receiving local anesthetic injections. Subjects who presented with superficial lacerations were randomly assigned to 2 groups, the first group received ice packing prior to injection and the second did not. The pain severity, length and depth of the laceration, and the other necessary information before and after the pain-reducing intervention were measured, documented, and compared at the end of the study. Pain scores were measured using a numerical rating scale before and after the procedure. The pain scores in the cryotherapy group were significantly lower before and after the procedure ($p < 0.001$). There was no statistically significant difference between the 2 groups for wound infection ($p = 0.783$). This study concluded that cooling the injection site prior to local anesthetic injection is an effective and inexpensive method to reduce the pain and discomfort caused by the injection.

2.4 Literature related to cryotherapy and arteriovenous fistula puncture related pain.

Lijiya and Diana (2015) performed a study to assess the effectiveness of cryotherapy on arteriovenous fistula puncture related pain among hemodialysis patients. Quasi experimental time series design was adopted with 50 samples. Pain

and behavioral response to pain was assessed in both the control and experimental group using the numerical rating scale and observational checklist during arteriovenous fistula puncture. During posttest the calculated t value was t1=4.21, t2=6.21 statistically significant at 0.05level. The findings of the study concluded that cryotherapy was effective in reducing subjective pain and objective behavioral response scores of arteriovenous fistula puncture related pain.

Golda, Revathi, Subhashini, Mathew and Indira, (2016) conducted a study to assess the effect of cold application on pre procedure pain during arteriovenous fistula puncture. A simple random sampling technique was used with 60 patients who are undergoing hemodialysis. Subjective pain was done using numerical rating scale. The study finding reveals that the subjective pain scores were found to be significantly ($p = 0.01$) reduced within the experimental group by cold application.

Dumbre (2008) attempted a study to assess the effectiveness of cryotherapy on pain during puncture of arteriovenous fistula among the patients on hemodialysis. Post-test only control group research design was adapted with 60 samples undergoing hemodialysis. Numerical pain rating scale and modified objective behavioral tool were used to assess the pain. The mean pain score by numerical rating scale in the experimental group was 4.07 + 1.46 and that of control group was 7 + 1.74 which is significant as $p< 0.0001$. The mean pain score by modified behavioural tool in experimental group was 2.30 + 1.78 and that of control group 5.60 + 1.92, which is significant as p value < 0.0001. This study revealed that cryotherapy effective on pain during puncture of arteriovenous fistula among the patients on hemodialysis (p value is <0.0001).

Aghajanloo, Ghafourifard, Haririan, and Gheydari (2016) conducted a study to comparison of the effects of cryotherapy and placebo on reducing the pain of arteriovenous fistula cannulation among hemodialysis patients A randomized clinical trial was conducted among 50 patients undergoing hemodialysis by random sampling method. Pain perception of the patients was recorded during two consecutive hemodialysis sessions using a visual analogue scale. With cryotherapy, scores of AVF puncture-related pain significantly reduced from 5.9±0.96 in session one (routine care) to 3.2±1.71 in session two of hemodialysis. However, no significant difference was observed between the two sessions in patients of the control group ($p=0.07$). According to the results of this study, cryotherapy, as a non-pharmacological and complementary approach, could be effective in the prevention of the pain associated with AVF cannulation.

Patidar (2015) conducted a study to assess the effectiveness of cryotherapy on pain during arteriovenous fistula puncture among hemodialysis patients. A quantitative pre-experimental research design was used with 60 hemodialysis patients with AV fistula by non-probability purposive sampling. Pain scale was used for data collection and cryotherapy as an intervention in relation to assess the level of pain during AV fistula puncture. A highly significant difference was found between pretest and posttest mean score on level of pain ($p<0.05$ at 5% level of significance). It was concluded that cryotherapy is an effective tool in reducing the level of pain during AV fistula puncture.

Attia and Hassan (2016) conducted a study to evaluate the effectiveness of cryotherapy in managing the pain at the puncture site of Arteriovenous Fistula (AVF) among children undergoing maintenance hemodialysis. A one group pre and post quasi experiment study was performed with 40 children in two HD centers affiliated with Cairo University. Before puncturing, cryotherapy was applied using 2 cm x3 cm pieces of frozen distilled water in a plastic bag. Pain was assessed subjectively and objectively in two dialysis sessions before and after cryotherapy. Pain was assessed using the Wonge Baker Faces Pain and the Observed Pain Behavior rating scales. Significant improvements were observed in respiratory rate before and after needle puncture and in oxygen saturation after needle puncture. A lower skin dryness was observed after cryotherapy (12.5%) than before cryotherapy (52.5%; $p < 0.001$). Cryotherapy can effectively reduce the venipuncture pain among children with AVF undergoing maintenance HD.

Shali (2012) performed a study to assess the outcome of cryotherapy on arteriovenous fistula puncture pain among patients on hemodialysis. Quasi experimental pre and post test with control group design was adapted with 60 clients undergone hemodialysis with arteriovenous fistula. Numerical pain rating scale was used to assess the pain level. Analysis revealed that, outcome of pain was a decrease in mean value 4.73 to 2.60 decrease in standard deviation form 0.91 to 0.67 respectively the 't' value 33.796 was found to be highly significant at $p<0.001$. In control group mean value from 5.13 to 4.97 and the standard deviation from 1.07 to 1.03 respectively the 't' value 0.623 was found to be not significant at $p = 0.538$. Study found that subjective pain score were significantly reduced within the experimental group. This study concluded that cryotherapy was an effective pain management technique.

Pachori (2016) attempted a study to assess the effectiveness of selected intervention on pain during puncture of arteriovenous fistula among patients on hemodialysis. Post-test only control group research design was used. All the subjects were assessed for pain and effectiveness of cryotherapy during puncture of arteriovenous fistula in experimental and without cryotherapy in control group. Results revealed that control group patients are having 6.47 pain score and experiment group are having 4.83 pain score, so the difference is 1.63. Control group patients are having 4.57 pain behavior score and experiment group are having 3.23 pain behavior score, so the difference is 1.33.The analysis of the data reveals that the cryotherapy is highly significant (p=0.01) experimental group for reduction of pain during puncture of arteriovenous fistula among the patients on hemodialysis than control group. The study concluded that the cryotherapy is an effective intervention to reduce pain during puncture of arteriovenous fistula among patients of hemodialysis.

Davtalab, Naji and Shahidi (2016) a study was conducted to compare and determine the effects of Valsalva maneuver and ice massage at Hoku point on pain intensity during arteriovenous fistula puncture in patients undergoing hemodialysis. This study was conducted with 70 hemodialysis patients who were selected by convenience sampling in two Amin Medical Center and Hazrat-e Zahra-e Marziye Hospital in Isfahan. Pain was assessed by Abbey pain scale and numerical pain rating scale. Finding showed that after intervention, objective pain rate in Valsalva maneuver group is significantly less than ice massage group (p=0.04). Valsalva maneuver method compared to ice massage method reduces the objective pain due to cannulation of arteriovenous fistula in patients undergoing hemodialysis, more efficiently.

Arab, Bagheri-Nesami, Mousavinasab, Espahbodi and Pouresmail (2017) performed a study to compare the effects of hegu point ice massage and 2% lidocaine gel on arteriovenous fistula puncture-related pain in hemodialysis patients. A randomized controlled trial with 70 hemodialysis patients were divided into two groups. The fistula puncture-related pain in the two groups was measured in the first session of hemodialysis without any intervention. During a hemodialysis session, 2% lidocaine gel was applied on the patient's arteriovenous fistula site in one group and other group received ice cube massage on the Hegu point in the hand without fistula in the other hemodialysis session. Visual Analogue Scale was used to assess the pain. Results showed that there was no significant differences in the mean pain scores of the two groups. This study revealed that lidocaine gel and hegu point ice massage affected the intensity of fistula puncture related pain in hemodialysis patients. Hegu point ice massage is recommended to be used for fast and safe pain reduction in hemodialysis patients.

Khakha, Mahajan, Gupta, Agarwal and Yadav (2008) conducted a study to assess the effect of cryotherapy on pain due to arteriovenous fistula puncture in hemodialysis patients. A randomized control trial was adopted with 60 patients using convenient sampling. Objective and subjective pain scoring was done on two consecutive days of HD treatment. Numerical rating scale was used to assess the subjective pain and objective pain was assessed using observation checklist. The study result showed that objective and subjective pain scores were found to be significantly ($p = 0.001$) reduced within the experimental group. This study recommended cryotherapy is an effective pain management.

Sundar, Gowri and Aruna (2017) conducted a study on evaluate the effectiveness of cryotherapy on arteriovenous fistula puncture site pain among patients on Haemodialysis. A Quasi-experimental design (pre-post test) was adopted with sixty samples by convenient sampling technique. Numerical pain rating scale was used in both groups. Posttest level of pain was assessed in both experimental and control group. Findings showed that in pre test, in experimental group, 14(46.67%) had moderate, 10(33.33%) had severe and 6(20%) had mild level of pain. In control group 15(50%) had moderate, 10(33.33%) had severe and 5(16.67%) had mild level of pain. In post test, in experimental group 14(46.67%) had mild, 13(43.33%) had moderate and only 3(10%) had severe level of pain. In control group, 16(53.33%) had moderate, 9(30%) had severe and 5(16.67%) had mild level of pain. It was statistically significant at $p < 0.001$. There was a statistically significant association with post test level of pain in the experimental group at $p<0.05$ level. This study revealed that cryotherapy is a simple, non-pharmacological and cost effective method in reducing pain among hemodialysis patients.

METHODOLOGY

This chapter deals with the description of research approach, research design, research setting, sampling technique, criteria for sample selection, variables of the study, tools for data collection, pilot study, procedure for data collection and techniques of data analysis and interpretation.

3.1 Research Approach

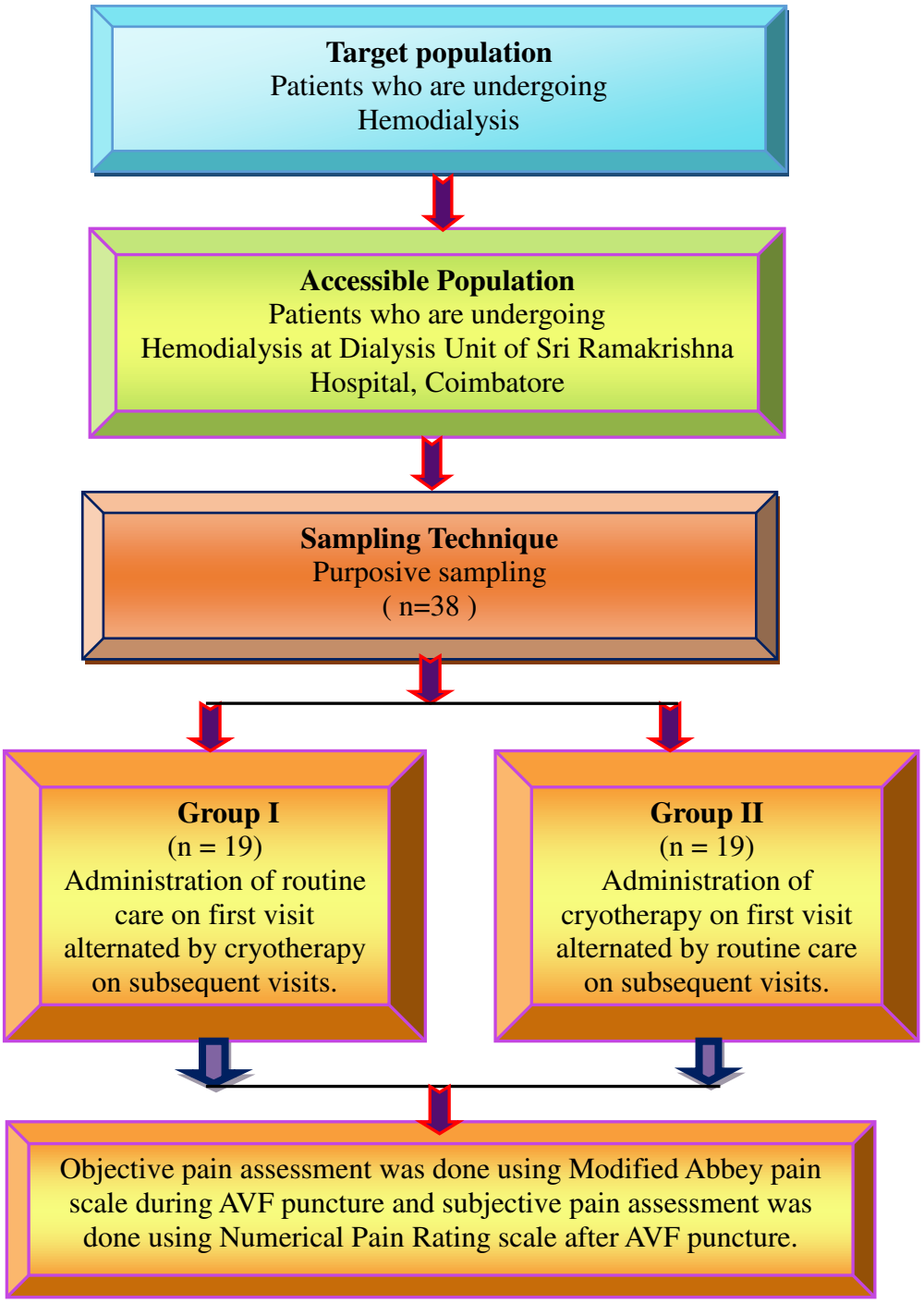
The present study aimed to assess the effect of cryotherapy on arteriovenous fistula puncture related pain among patients undergoing hemodialysis. The researcher manipulated the independent variable and measured the changes in the dependent variable. Hence in view of the nature of problem and to accomplish the objectives, quantitative research approach was adopted for the study.

3.2 Research Design

The research design used for the study was repeated measures cross over design. The samples were divided in to Group I and II. Group I patients received routine care on first visit alternated by cryotherapy on subsequent visits and Group II patients received cryotherapy on first visit alternated by routine care on subsequent visits. Hence the design was found to be appropriate to evaluate the effect of cryotherapy on arteriovenous fistula puncture related pain among patients undergoing hemodialysis.

Figure 3.1

Schematic representation of Research Design



3.3 Research Setting

The study was conducted in dialysis unit of Sri Ramakrishna Hospital Coimbatore, a 750 bedded super specialty hospital. It is situated two kilometers from Gandhipuram with accessible transport facilities. The total bed strength of dialysis unit is 20 beds. In the dialysis unit nearly, 60 patients undergo hemodialysis in four sessions throughout the day.

3.4 Research Population

Target population for the present study were patients who were undergoing hemodialysis. The accessible population included the patients who were undergoing hemodialysis by arteriovenous fistula at Sri Ramakrishna Hospital, Coimbatore.

3.5 Sampling and Sample Size

A total of 38 patients undergoing hemodialysis were selected for the study using Non probability - purposive sampling technique. Sample size was determined by the following formula.

$$n = \frac{N}{1 + Ne^2}$$

Where,

n = Sample size

N = Population

e = Derived error

N = 1375

e = 17% or 0.17

Sample size (n) =38

$$n = \frac{1375}{1 + 1375 \times (0.17)^2} = 35.7$$

3.6 Criteria for Sample Selection

The samples were selected based on the following inclusion and exclusion criteria.

3.6.1 Inclusion criteria

1. Patients who were alert and cooperative.
2. Patients who were undergoing hemodialysis for two or more cycles in a week.
3. Patients who were willing to participate.
4. Patient who had AV fistula at the forearm and were undergoing hemodialysis.
5. Patients who were regularly coming for hemodialysis.

3.6.2 Exclusion criteria

1. Patients with neurological disorders who were not able to perceive pain.

2. Patients having radiation injury, Raynaud disease and diabetic neuropathy.

3. Patients with femoral and jugular dialysis.

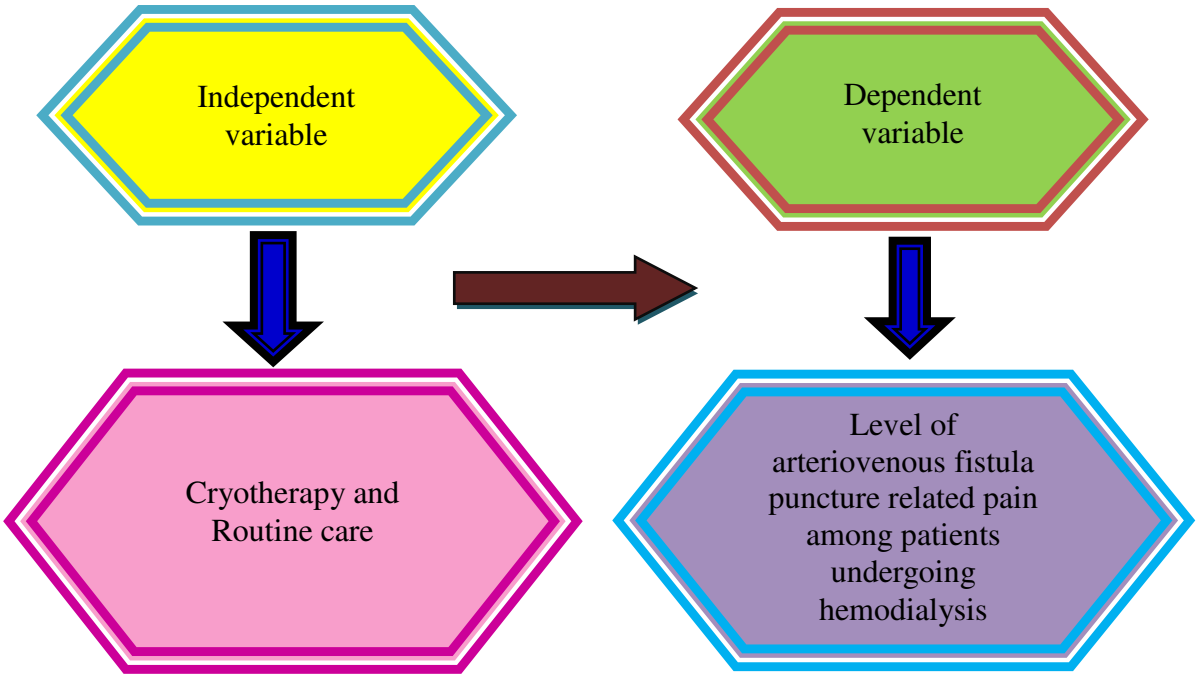
4. Patients who were undergoing emergency and first time hemodialysis.

3.7 Variables of Study

The independent variable in the present study is cryotherapy and routine care and dependent variable is the level of arteriovenous fistula puncture related pain among patients undergoing hemodialysis at Sri Ramakrishna hospital, Coimbatore.

Figure 3.2

Schematic Representation of Variables



3.8 Instruments and Tool used for data collection

The following tools were used for the data collection according to the expert's opinion and the supportive literatures.

The tool consisted of:

Section A : Demographic Data.

Section B : Physiological parameters

Section C : Modified Abbey pain scale for objective pain assessment.

Section D : Numerical Pain Rating scale for subjective pain assessment.

3.8.1 Questionnaire on demographic data

A questionnaire was designed to collect the demographic data related to age, gender, educational status, occupational status, family monthly income, duration of diagnosis of renal failure, duration of hemodialysis, duration of present arteriovenous fistula, presence of associated illness and number of hemodialysis cycles.

3.8.2 Physiological parameters

Physiological parameters included pulse rate, respiratory rate and blood pressure. These parameters were assessed before and after hemodialysis.

3.8.3 Modified Abbey pain scale

This tool was developed by Abbey J., De Bellis A., Piller N., Esterman A., Giles L., Parker D and Lowcay B in the year 2002 and it had six part that included vocalization, facial expression, change in body language, behavioural change, physiological change, and physical change. This tool was modified by the researcher. Four parts such as vocalization, facial expression, change body language and mood changes were included. It was utilized to assess objective type of pain during arteriovenous fistula puncture.

The scores were interpreted as follows:

Table no: 3.1 Level of pain score of objective pain

Level of pain	scores
No pain	0-3
Mild pain	4-6
Moderate pain	7-9
Severe pain	10-12

3.8.4 Numerical Pain Rating scale :

It was developed by the McCaffery and Beebe for subjective pain assessment. The scale consisted of numerical value from zero to ten.

The scores were interpreted as follows:

Table no: 3.2 Level of pain score of subjective pain

Level of pain	scores
No pain	0
Mild pain	1-3
Moderate pain	4-6
Severe pain	7-10

3.9 Cryotherapy

Cryotherapy was given on the web between thumb and index finger of the opposite hand (contralateral) 10minutes before the arteriovenous fistula puncture and continued until arteriovenous puncture (approximately 2 minutes). Cryotherapy was given for both groups in alternative visits.

3.10 Validity of the Tool

Validity refers to whether an instrument accurately measures what it is supposed to measure. The tool was validated by three experts in the field of medical surgical nursing speciality. The experts were requested to give their opinion and suggestions regarding relevance, appropriateness, accuracy and degree of agreement in each item of the tool. Suggestions and recommendations given by the experts were accepted and necessary corrections were done. The tool was found to have high content validity.

3.11 Reliability of the Tool

The scientific reliability of numerical rating pain scale for subjective pain assessment and Modified Abbey pain scale for objective pain assessment tools were tested in several studies. In Fareed et al study (2014), the test-retest method and Pearson correlation coefficient formula was used. The reliability was found to be 0.94 for numerical rating pain scale and 0.87 for modified abbey pain scale.

3.12 Ethical Consideration

The proposed study and tool were presented to the institutional ethical committee and the same was approved by the committee members. Ethical clearance approval for the present study was obtained from Institutional Ethical Committee of Sri Ramakrishna Hospital, Coimbatore. The ethical committee has given a written consent to proceed the study. Each participant was explained about the study and written consent was obtained.

3.13 Pilot Study

The pilot study was conducted at Sri Ramakrishna Hospital, Coimbatore from 7.11.17 to 13.11.17 for check the feasibility and practicability of the tool. Ten patients who fulfilled the inclusion criteria were selected by simple random sampling technique. The researcher developed rapport with the patients. Written consent was obtained from the patients. Demographic data was collected. Group I and II consist of five patients each and received cryotherapy and routine treatment in alternative visits. Physiological parameters were checked before and after for both groups. Assessment was done Modified Abbey pain scale for objective pain assessment during AVF puncture and Numerical Rating pain scale for subjective

pain assessment after AVF puncture for both groups. The results were analyzed based on the scores obtained by the samples. The analysis shows that, there was a significant difference between groups at 0.001 level of significance. The sample size and settings was accessible for this study.

3.13.1 Changes after Pilot study

Assessment of temperature in physiological parameters before and after the cryotherapy were excluded. Modified Abbey pain scale tool was changed as four parts instead of six parts such as vocalization, facial expression, change in body language, and mood change. The researcher selects the patient as group I and group II by purposive sampling technique. Group I patients receives routine care on first visit alternated by cryotherapy on subsequent visits and Group II patients receives cryotherapy on first visit alternated by routine care on subsequent visits.

3.14 Procedure for Data Collection

The main study was conducted at Sri Ramakrishna Hospital, Coimbatore from 24.11.17 to 23.12.17. The validated tool was used for data collection and the main study was conducted over a period of four weeks. Demographic data were collected in both group I and II. Group I patients receives routine care on first visit alternated by cryotherapy on subsequent visits and Group II patients receives cryotherapy on first visit alternated by routine care on subsequent visits. Physiological parameters were monitored before and after interventions. Cryotherapy is the application of ice gel pack wrapped in gauzes and placed on the web between thumb and index finger of the opposite hand (contralateral). It was applied 10minutes before the arteriovenous fistula puncture and continued up

to arteriovenous puncture (approximately 2 minutes) and assessed the level of arteriovenous fistula puncture related pain by using Modified Abbey pain scale for objective pain assessment during AVF puncture and Numerical Pain Rating scale for subjective pain assessment after AVF puncture for both groups.

3.15 Technique of Data Analysis and Interpretation

The frequency tables were formulated for all significant information. Descriptive and inferential statistical methods (paired 't' test, student 't' test and Karl Pearson's coefficient correlation) were used for data analysis. Descriptive statistical method was applied for the analysis of demographic variables. Inferential statistical methods were used to identify the effect of cryotherapy.

3.15.1 Paired 't' test

Paired 't' test was used to find out the significance of cryotherapy

$$|t| = \left| \frac{\bar{d}}{S / \sqrt{n}} \right|$$

Where,

$\bar{d}$ = Mean of difference

S = $\sqrt{\frac{1}{n-1}\left[\sum d^2 - \frac{(\sum d)^2}{n}\right]}$

N = Total number of observation

3.15.2 Student ‘t’ test

Student 't' test was used to analyze the effect of cryotherapy on arteriovenous fistula puncture related pain using Numerical subjective pain assessment scale among cryotherapy and routine care.

$$|t| = \left| \frac{\overline{X} - \overline{Y}}{S\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}} \right|$$

Where,

$\overline{X}$ = Mean Pain scores of the routine care

$\overline{Y}$ = Mean Pain scores of the cryotherapy

S = $\sqrt{\frac{1}{n_1 + n_2 - 2}\left[\sum(x - \bar{x})^2 + \sum(y - \bar{y})^2\right]}$

n_1 = Total number of observations in routine care

n_2 = Total number of observation in cryotherapy

3.15.3 Karl Pearson's Coefficient Correlation

Karl Pearson's Coefficient Correlation was used to correlate the level of arteriovenous fistula puncture related pain observed using Modified Abbey pain scale and Numerical Pain Rating scale among patient undergoing hemodialysis.

$$\mathbf{r} = \frac{\sum(X-\overline{X})(Y-\overline{Y})}{\sqrt{\sum(X-\overline{X})^2 \sum(Y-\overline{Y})^2}}$$

$\overline{X}$ = mean pain observed using Modified Abbey pain scale scores.

$\overline{Y}$ = mean pain observed using Numerical Pain Rating scale scores.

DATA ANALYSIS AND INTERPRETATION

This chapter deals with the analysis and results of the data collected from 38 patients undergoing hemodialysis through arteriovenous fistula. Aim of the study was to determine the effect of cryotherapy on arteriovenous fistula puncture related pain among patients undergoing hemodialysis. Patients were selected based on the inclusion and exclusion criteria for this study. Interventions selected for this study are cryotherapy and routine care. The level of objective pain assessment was done using Modified Abbey pain scale and subjective pain assessment was done using Numerical Pain Rating scale after arteriovenous fistula puncture.

Descriptive and Inferential statistical methods are used to analyze the data. Frequency, percentage, mean and standard deviation are used to present the demographic variables and the level of objective and subjective pain. Inferential statistical methods were used to analyze the effect of cryotherapy on arteriovenous fistula puncture related pain among the patients undergoing hemodialysis. Student‘t’ test was used to analyze the effect of cryotherapy on arteriovenous fistula puncture related pain among patients undergoing hemodialysis. Paired ‘t’ test was used to analyse the effect of cryotherapy on the physiological parameters in Group I and II. Karl Pearson Coefficient of Correlation was used to find out the correlation between the level of arteriovenous fistula puncture related pain observed using Numerical Subjective Pain Rating scale and Modified Abbey Objective Pain Rating scale.

ORGANIZATION OF THE FINDINGS

Data obtained from the patients undergoing hemodialysis were organized, analyzed and presented under the following sections.

Section I

Demographic variables of patients undergoing hemodialysis.

Section II

Assessment of physiological parameters among patients undergoing hemodialysis.

Section III

Assessment on level of arteriovenous fistula puncture related pain among patients undergoing hemodialysis.

Section IV

Effect of cryotherapy on arteriovenous fistula puncture related pain among patients undergoing hemodialysis.

Section V

Correlation between the arteriovenous fistula puncture related pain observed using Modified Abbey pain scale and Numerical Pain Rating scale.

Section I

Demographic Variables of Patients Undergoing Hemodialysis

The demographic variables such as age, gender, educational status, occupational status, family monthly income, duration of diagnosis of renal failure, duration of hemodialysis treatment, duration of present arteriovenous fistula, associated illness and number of hemodialysis cycles per week were analyzed using descriptive statistics in terms of frequency and percentage. Analyzed data were presented in the form of tables and diagrams.

Table 4.1.1

Age of Patients undergoing Hemodialysis

n=38

S. No	Age (in years)	Number of Patients	
		Frequency	Percentage (%)
1	31-40	5	13.16
2	41-50	4	10.53
3	51-60	13	34.21
4	61-70	16	42.10

The above table 4.1.1 depicts that among 38 patients, 16 (42.10%) patients were between the age group of 61-70 years, 13 (34.21%) patients were between the age group of 51-60 years, 5 (13.16%) patients were between the age group of 31- 40 years and 4 (10.53%) patients were between the age group of 41-50 years.

Figure 4.1.1

Age of Patients undergoing Hemodialysis

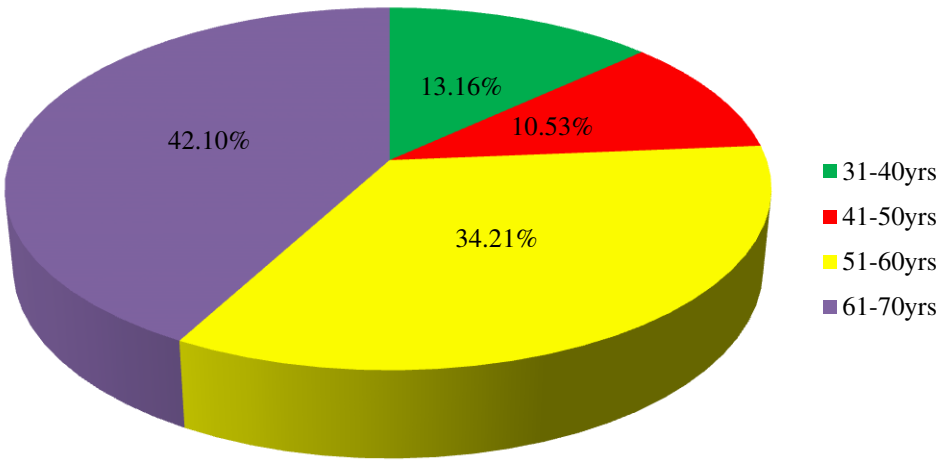


Table 4.1.2

Gender of patients undergoing Hemodialysis

n=38

S. No	Gender	Number of Patients	
		Frequency	Percentage (%)
1	Male	29	76.32
2	Female	9	23.68

The above table 4.1.2 shows that among 38 patients, the majority of patients were males 29 (76.32%) and 9 (23.68%) were females.

Figure 4.1.2

Gender of patients undergoing Hemodialysis

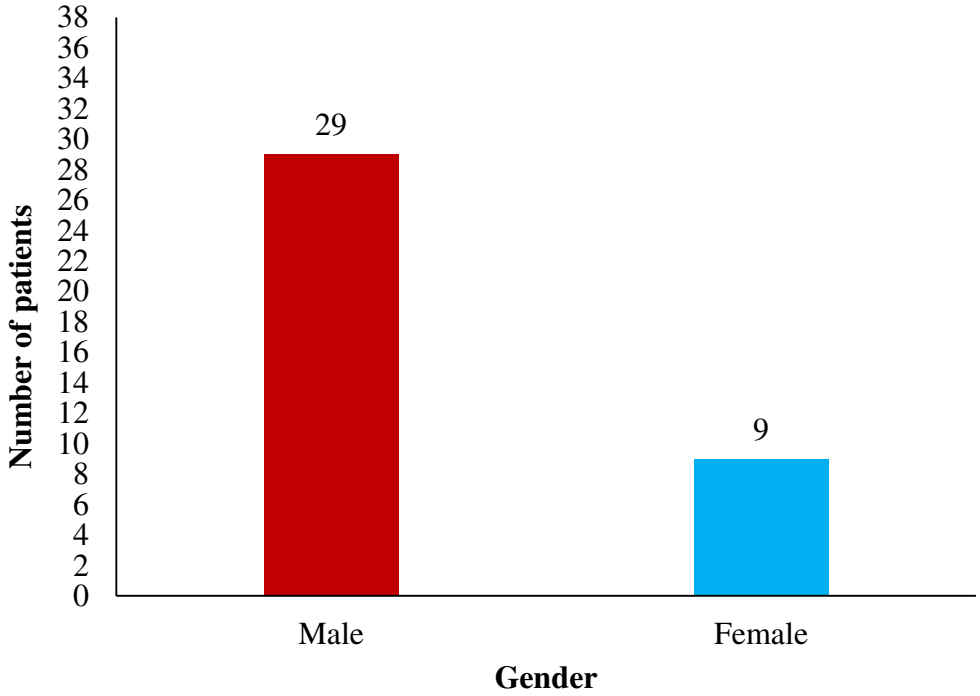


Table 4.1.3

Educational status of patients undergoing Hemodialysis

n=38

S. No	Education	Number of Patients	
		Frequency	Percentage (%)
1	Illiterate	6	15.79
2	Primary school	4	10.53
3	Middle school	3	7.89
4	High school	4	10.53
5	Higher secondary	7	18.42
6	Graduate and Post graduate	14	36.84

The above table 4.1.3 represents the distribution of patients based on their educational status. The findings show that, 14(36.84%) patients were graduates, 7(18.42%) had higher secondary education, 4(10.53%) patients had primary school education and high school education respectively, 3(7.89%) patients had middle school education and 6(15.79%) of them were illiterates.

Figure 4.1.3

Educational status of patients undergoing Hemodialysis

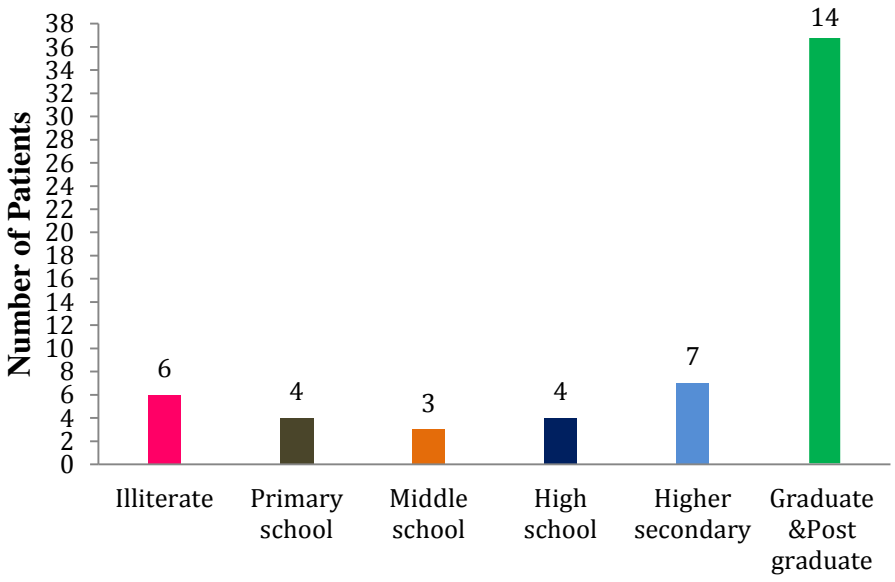


Table 4.1.4

Occupational status of patients undergoing Hemodialysis

n=38

S. No	Occupation	Number of Patients	
		Frequency	Percentage (%)
1	Employed	8	21.05
2	Unemployed	30	78.95

The above table 4.1.4 depicts the occupational status of patients undergoing hemodialysis. Majority 30 (78.95%) of patients were unemployed and only 8 (21.05%) of them were employed.

Figure 4.1.4

Occupational status of patients undergoing Hemodialysis

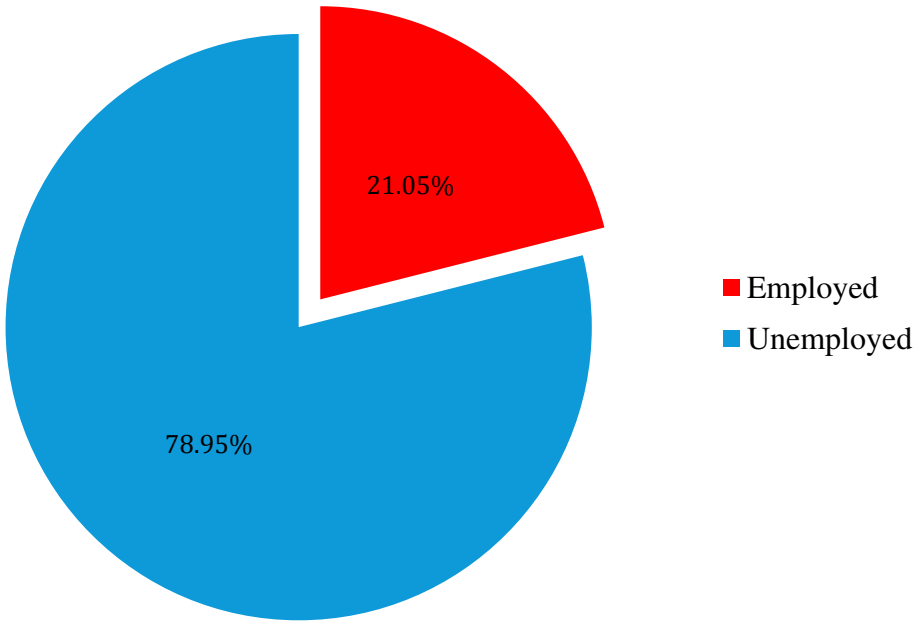


Table 4.1.5

Family Monthly Income of patients undergoing Hemodialysis

n = 38

S. No	Family Monthly Income (₹)	Number of Patients	
		Frequency	Percentage (%)
1	< 5000	0	0
2	5001 – 10,000	0	0
3	10,001 – 15,000	14	36.84
4	> 15,001	24	63.16

The above table 4.1.5 reveals the family monthly income of patients undergoing hemodialysis. Majority 24 (63.16%) of patients had a family monthly income of above ₹15,001 and the remaining 14 (36.84%) patients had a family monthly income between ₹ 10,001 – 15,000.

Figure 4.1.5

Family Monthly Income of patients undergoing Hemodialysis

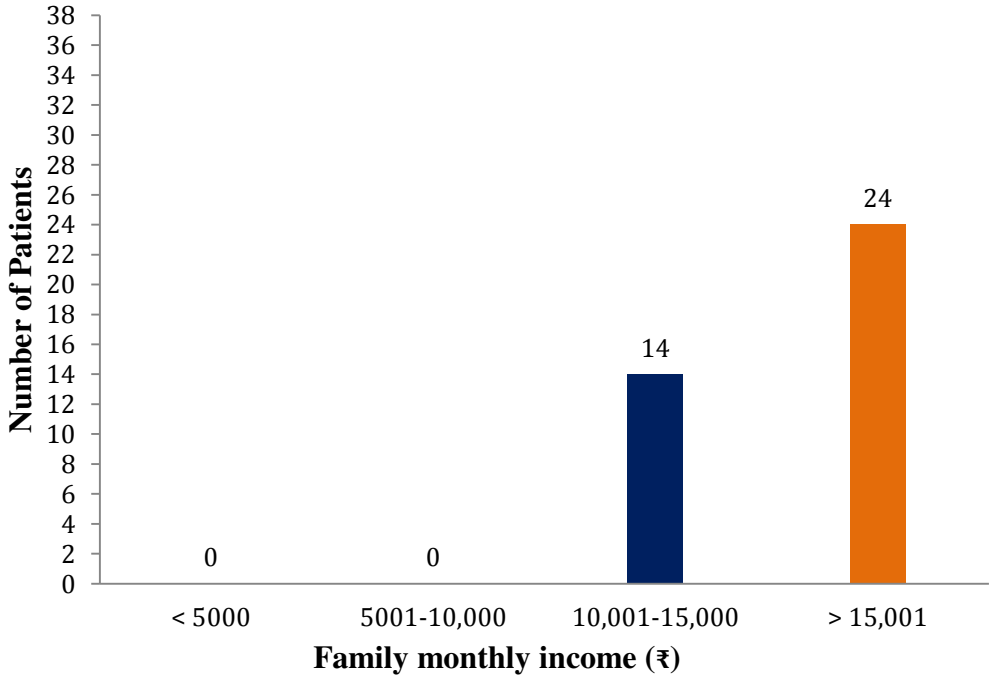


Table 4.1.6

Duration of Diagnosis of Renal Failure among patients undergoing Hemodialysis

n = 38

S. No	Duration of Diagnosis of Renal Failure (in years)	Number of Patients	
		Frequency	Percentage (%)
1	<1	13	34.21
2	1-10	24	63.16
3	11-20	1	2.63

The above table 4.1.6 describes the distribution of the patients based on the duration of diagnosis of renal failure. Results of the study shows that, majority 24 (63.16%) of patients suffered from renal failure for the past 10 years, 13 (34.21%) patients were diagnosed less than one years and one patient was diagnosed with renal failure between 11-20 years.

Figure 4.1.6

Duration of Diagnosis of Renal Failure among patients undergoing Hemodialysis

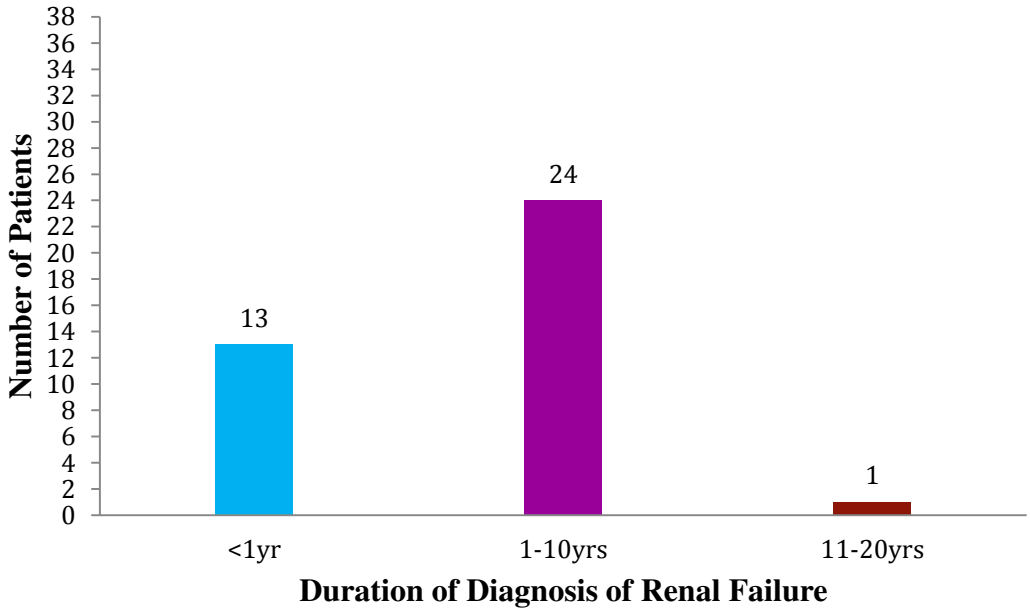


Table 4.1.7

Duration of Hemodialysis among patients with chronic renal failure

n=38

S. No	Duration of Hemodialysis (in years)	Number of Patients	
		Frequency	Percentage (%)
1	<1	17	44.74
2	1-5	21	55.26

The above table 4.1.7 depicts the duration of hemodialysis among patients with renal failure. Results of the study shows that, 21 (55.26%) of them were on hemodialysis for 1 to 5 years, and 17 (44.74%) were on dialysis for less than one year.

Figure 4.1.7

Duration of Hemodialysis among patients with chronic renal failure

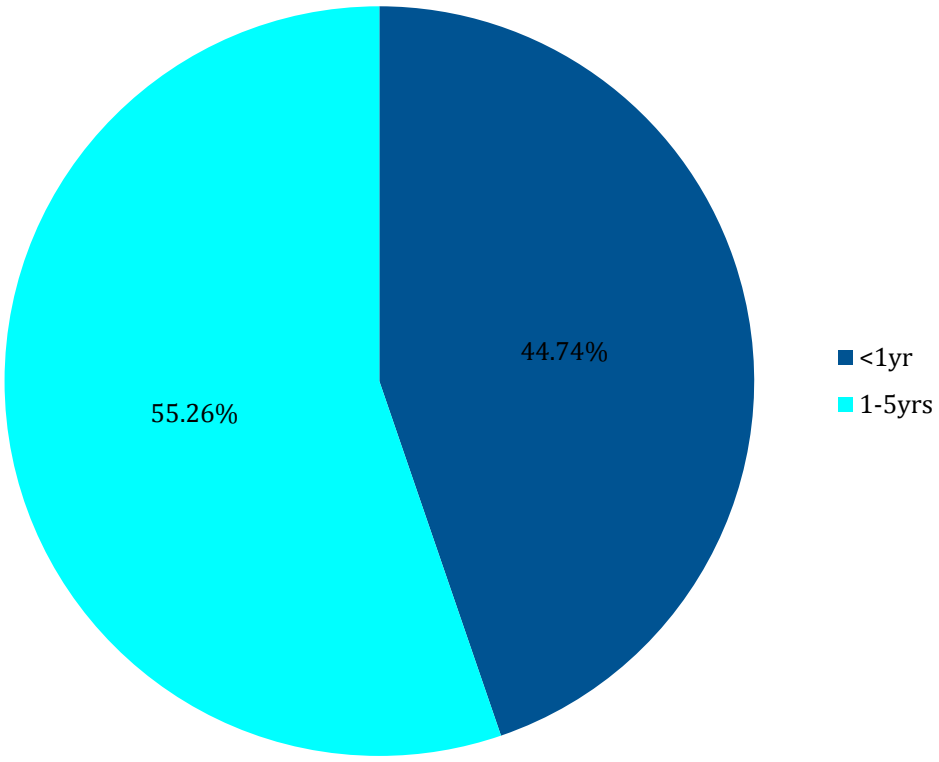


Table 4.1.8

Duration of Present Arteriovenous Fistula among patients undergoing Hemodialysis

n=38

S. No	Duration of present arteriovenous fistula use (in months)	Number of Patients	
		Frequency	Percentage (%)
1	1-6	13	34.21
2	7-12	8	21.05
3	13-18	7	18.42
4	19-24	10	26.32

The above table 4.1.8 represents the duration of present arteriovenous fistula. Findings revealed that, 13 (34.21%) patients had the arteriovenous fistula for the past 1-6 months, 10 (26.32%) patients had arteriovenous fistula for 19-24 months, 8 (21.05%) patients were on arteriovenous fistula for 7-12 months and 7 (18.42%) had the arteriovenous fistula for the past 13-18 months.

Figure 4.1.8
Duration of Present Arteriovenous Fistula among patients undergoing Hemodialysis

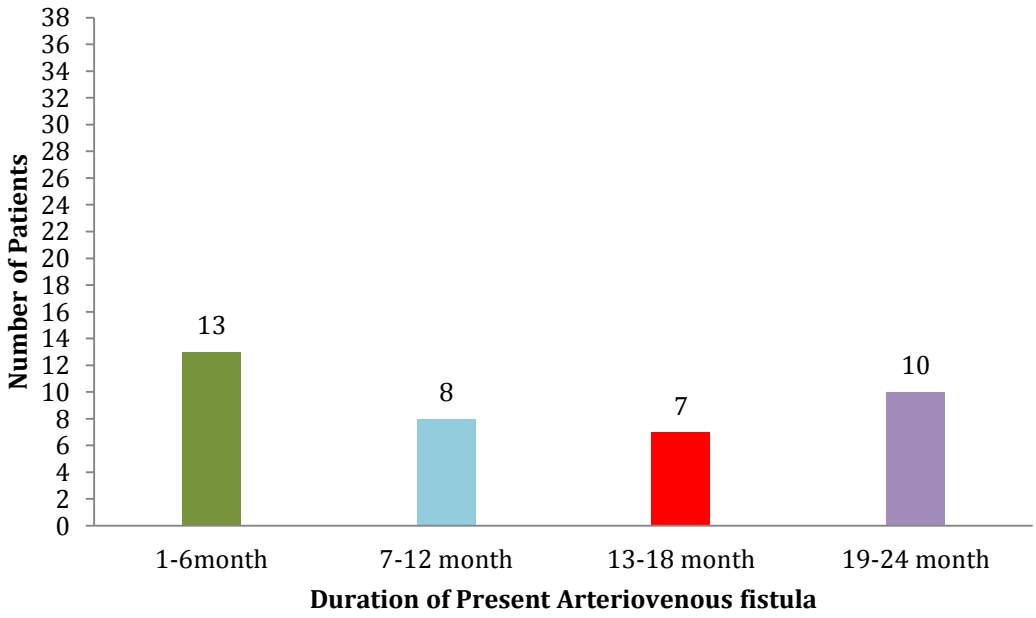


Table 4.1.9

Associated Illness among patients undergoing Hemodialysis

n=38

S. No	Associated illness	Number of Patients	
		Frequency	Percentage (%)
1	Present	37	97.37
2	Absent	1	2.63

The above table 4.1.9 reveals the presence of associated illness among patients undergoing hemodialysis and the findings showed that, majority 37 (97.37%) of patients had associated illnesses along with renal failure such as Diabetes Mellitus, Hypertension, Hepatitis, Anaemia and cardiac problems.

Figure 4.1.9

Associated Illness among patients undergoing Hemodialysis

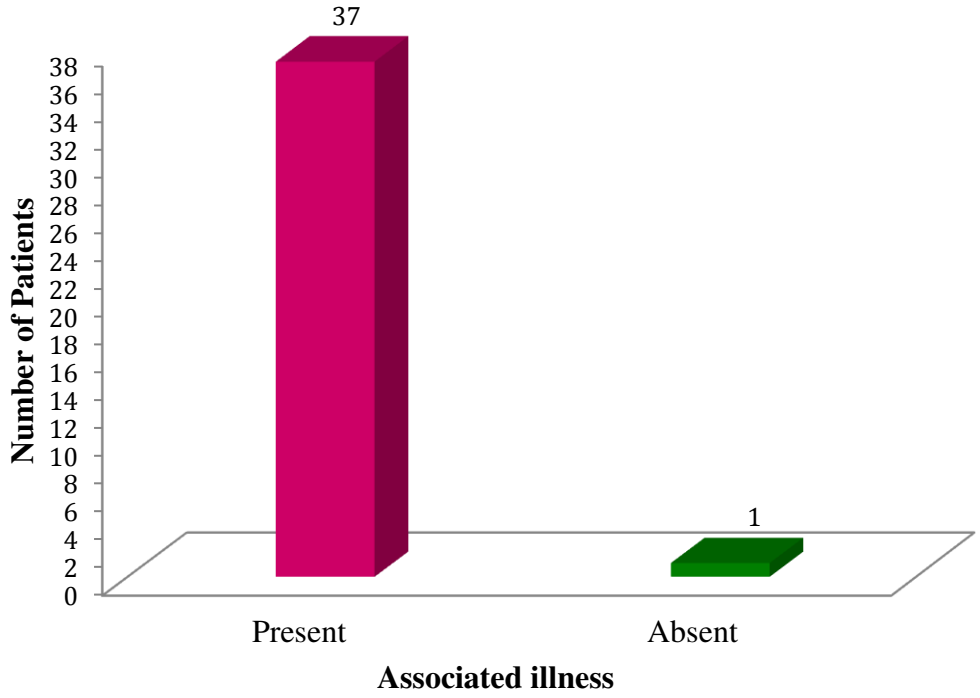


Table 4.1.10

Number of Hemodialysis cycles among Patients undergoing Hemodialysis

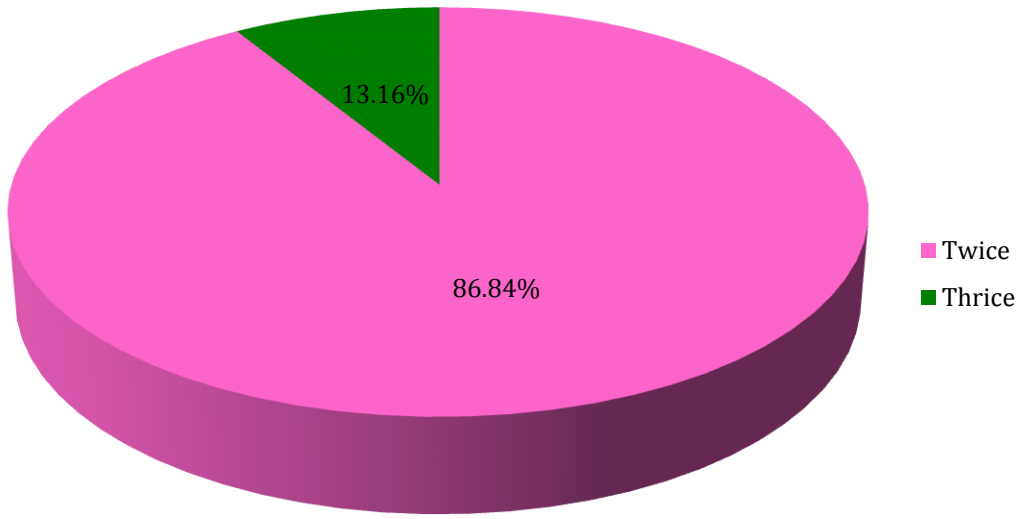
n=38

S. No	Number of Hemodialysis cycles (per week)	Number of Patients	
		Frequency	Percentage (%)
1	Two	33	86.84
2	Three	5	13.16

The above table 4.1.10 shows that, majority 33 (86.84%) of patients were on hemodialysis cycles twice a week and 5 (13.16%) patients were on hemodialysis thrice a week.

Figure 4.1.10

Number of Hemodialysis cycles among Patients undergoing Hemodialysis



Section II

Assessment of physiological parameters among patients undergoing hemodialysis.

Physiological parameters such as pulse rate, respiratory rate and blood pressure were assessed before and after each sitting of the hemodialysis among the patients undergoing hemodialysis. Collected data were organized, analyzed and presented using descriptive statistics.

Table 4.2.1

Assessment on level of Physiological Parameters among Patients undergoing Hemodialysis in Group I

S. No	Physiological parameters	Routine care (n=19)				Cryotherapy (n=19)			
		Before		After		Before		After	
		Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)
1	**Pulse rate (bpm)**								
	60-70	4	21.05	4	21.05	2	10.53	4	21.05
	71-80	4	21.05	5	26.32	7	36.84	9	47.37
	81-90	10	52.64	9	47.37	7	36.84	4	21.05
	91-100	1	5.26	1	5.26	2	10.53	2	10.53
	101-110	0	0	0	0	1	5.26	0	0
2	**Respiratory rate (bpm)**								
	15-20	10	52.63	10	52.63	9	47.37	9	47.37
	21-25	9	47.37	9	47.37	10	52.63	10	52.63
	26-30	0	0	0	0	0	0	0	0
	31-35	0	0	0	0	0	0	0	0
3	**Systolic blood pressure (mmHg)**								
	<110	0	0	0	0	0	0	0	0
	110-130	2	10.53	2	10.53	1	5.26	1	5.26
	131-150	3	15.78	3	15.78	6	31.58	7	36.84
	151-170	8	42.11	9	47.37	7	36.84	6	31.58
	>170	6	31.58	5	26.32	5	26.32	5	26.32
4	**Diastolic blood pressure (mmHg)**								
	60-70	1	5.26	1	5.26	0	0	1	5.26
	71-80	3	15.79	5	26.32	1	5.26	2	10.53
	81-90	6	31.58	7	36.84	6	31.58	12	63.16
	91-100	5	26.32	3	15.79	9	47.37	4	21.05
	101-110	4	21.05	3	15.79	3	15.79	0	0

The table 4.2.1 represents the physiological parameters such as pulse rate, respiratory rate and blood pressure level among patients undergoing hemodialysis in Group I. Results of the study indicates that, majority 10 (52.64%) of patients receiving routine care prior to arteriovenous fistula puncture had pulse rate of 81-90 bpm and majority 9 (47.37%) patients receiving after routine care had pulse rate of 81-90 bpm. Among 19 patients, 1 (5.26%) patient had a pulse rate of 91-100 bpm before routine care and after arteriovenous fistula puncture.

Majority 7 (36.84%) of patients receiving cryotherapy prior to arteriovenous fistula puncture had pulse rate of 71-80 bpm and 81-90 bpm whereas, majority 9 (47.37%) of patients had a pulse rate of 71-80 bpm after arteriovenous fistula puncture. Among 19 patients, 2 (10.53%) patient had a pulse rate of 91-100 bpm before routine care and after arteriovenous fistula puncture.
There were no changes present in respiratory rate before and after routine care and cryotherapy in group I patients.

Majority 8 (42.11%) of patients receiving routine care prior to arteriovenous fistula puncture had a systolic blood pressure of 151-170 mmHg and majority 9 (47.37%) of patients receiving routine care after arteriovenous fistula puncture had a systolic blood pressure of 151-170 mmHg. Among 19 patients, 2 (10.53%) patients had a systolic blood pressure of 110-130 mmHg before routine care and after arteriovenous fistula puncture.

Majority 7 (36.84%) of patients had a systolic blood pressure of 151-170 mmHg before cryotherapy and after arteriovenous fistula puncture had a systolic blood pressure of 131-150 mmHg. Among 19 patients, 1 (5.26%) patient had a systolic blood pressure of 110-130 mmHg before routine care and after arteriovenous fistula puncture.

Majority 6(31.58%) of patients receiving routine care prior to arteriovenous fistula puncture had a diastolic blood pressure of 81-90 mmHg and majority 7(36.84%) of patients receiving routine care after arteriovenous fistula puncture had a diastolic blood pressure of 81-90 mmHg. Among 19 patients, 1(5.26%) patient had a diastolic blood pressure of 60-70 mmHg before routine care and after arteriovenous fistula puncture.

Majority 9 (47.37%) of patients receiving cryotherapy prior to arteriovenous fistula puncture had a diastolic blood pressure of 91-100 mmHg and majority 12 (63.16%) of patients receiving routine care after arteriovenous fistula puncture had a diastolic blood pressure of 81-90 mmHg. Among 19 patients, 1 (5.26%) patient had a diastolic blood pressure of 60-70 mmHg and 71-80 mmHg before routine care and after arteriovenous fistula puncture.

Table 4.2.2

Assessment on level of physiological parameters among Patients undergoing Hemodialysis in Group II

S. No	Physiological parameters	Cryotherapy (n=19)				Routine care (n=19)			
		Before		After		Before		After	
		Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)
1	**Pulse rate (bpm)**								
	60-70	5	26.32	7	36.84	3	15.79	3	15.79
	71-80	5	26.32	4	21.05	6	31.58	6	31.58
	81-90	4	21.04	3	15.79	3	15.79	5	26.32
	91-100	5	26.32	5	26.32	6	31.58	4	21.05
	101-110	0	0	0	0	1	5.26	1	5.26
2	**Respiration rate (bpm)**								
	15-20	2	10.53	6	31.58	1	5.26	2	10.53
	21-25	15	78.94	11	57.89	12	63.16	12	63.15
	26-30	2	10.53	2	10.53	6	31.58	5	26.32
	31-35	0	0	0	0	0	0	0	0
3	**Systolic blood pressure (mmHg)**								
	<110	0	0	0	0	0	0	0	0
	110-130	1	5.26	2	10.53	2	10.53	1	5.26
	131-150	4	21.06	5	26.31	2	10.53	3	15.79
	151-170	11	57.89	10	52.63	10	52.63	9	47.37
	>170	3	15.79	2	10.53	5	26.31	6	31.58
4	**Diastolic blood pressure (mmHg)**								
	60-70	1	5.26	1	5.26	0	0	0	0
	71-80	3	15.79	3	15.79	0	0	1	5.26
	81-90	12	63.16	12	63.16	5	26.32	6	31.58
	91-100	3	15.79	3	15.79	11	57.89	10	52.63
	101-110	0	0	0	0	3	15.79	2	10.53

The table 4.2.2 represents the physiological parameters such as pulse rate, respiratory rate and blood pressure level among patients undergoing hemodialysis in Group II. Results of the study revealed that, majority 5 (26.32%) of the patients receiving cryotherapy prior to arteriovenous fistula puncture had pulse rate of 60-70 bpm, 71-80 bpm, and 91-100 bpm. Whereas, majority 7 (36.84%) of patients had pulse rate of 60-70 bpm after arteriovenous fistula puncture. Among 19 patients, 3 (15.79%) patients had a pulse rate of 81-90 bpm after arteriovenous fistula puncture.

Majority 6 (31.58%) of the patients receiving routine care prior to arteriovenous fistula puncture had pulse rate of 71-80 bpm and 91-100 bpm. Whereas, majority 6 (31.58%) of the patients had a pulse rate of 71-80 bpm after arteriovenous fistula puncture. Among 19 patients, 1 (5.26%) patient had a pulse rate of 101-110 bpm before routine care and after arteriovenous fistula puncture.
Majority 15 (78.94%) of patients receiving cryotherapy prior to arteriovenous fistula puncture had respiratory rate of 21-25 bpm. Whereas, majority 11 (57.89%) of patients had respiratory rate of 21-25 bpm after arteriovenous fistula puncture. Among 19 patients, 2 (10.53%) patient had a pulse rate of 26-30 bpm before routine care and after arteriovenous fistula puncture.

Majority 12 (63.16%) of patients had a respiratory rate of 21-25 bpm before routine care and after arteriovenous fistula puncture. Among 19 patients, 1 (5.26%) patient receiving cryotherapy prior to arteriovenous fistula puncture had respiratory rate of 15-20 bpm. Whereas, 2 (10.53%) had a respiratory rate of 15-20 bpm after arteriovenous fistula puncture.

Majority 11 (57.89%) of patients receiving cryotherapy prior to arteriovenous fistula puncture had a systolic blood pressure of 151-170 mmHg and majority 10 (52.63%) after arteriovenous fistula puncture had a systolic blood pressure of 151-170 mmHg. Among 19 patients, 1 (5.26%) patient receiving cryotherapy prior to arteriovenous fistula puncture had a systolic blood pressure of 110-130 mmHg. Whereas, 2 (10.53%) patients had a systolic blood pressure of 110-130 mmHg after arteriovenous fistula puncture.

Majority 10 (52.63%) of patients receiving routine care prior to arteriovenous fistula puncture had a systolic blood pressure of 151-170 mmHg and majority 9 (47.37%) receiving routine care after arteriovenous fistula puncture had a systolic blood pressure of 151-170 mmHg. Among 19 patients, 2 (10.53%) patients receiving routine care prior to arteriovenous fistula puncture had a systolic blood pressure of 110-130 mmHg. Whereas, 1 (5.26%) patient had a systolic blood pressure of 110-130 mmHg after arteriovenous fistula puncture.

Majority 12 (63.16%) of patients had a diastolic blood pressure of 81-90 mmHg before cryotherapy and after arteriovenous fistula puncture. Among 19 patients, 1 (5.26%) patient had a diastolic blood pressure of 60-70 mmHg before cryotherapy and after arteriovenous fistula puncture.

Majority 11 (57.89%) of patients receiving routine care prior to arteriovenous fistula puncture had a diastolic blood pressure of 91-100 mmHg and majority 10 (52.63%) receiving routine care after arteriovenous fistula puncture had a diastolic blood pressure of 91-100 mmHg. Among 19 patients, 3 (15.79%) patient receiving routine care prior to arteriovenous fistula puncture had a diastolic blood pressure of 101-110 mmHg. 1 (5.26%) had a diastolic blood pressure of 71-80 mmHg after arteriovenous fistula puncture.

Table 4.2.3

Analysis on the effect of cryotherapy on physiological parameters among Patients undergoing Hemodialysis in Group I

n=19

S. No	Physiological parameters	Study group	Observations	Mean	SD	Mean difference	Calculated 't' value
1	Pulse rate	Routine care	Before	81	8.06	1.7	8.5***
			After	79.3	8.1		
		Cryotherapy	Before	82.12	8.4	4.2	10.5***
			After	77.9	8.2		
2	Respiratory rate	Routine care	Before	20.8	1.8	0.4	4***
			After	20.4	1.7		
		Cryotherapy	Before	21.04	2.1	0.54	3.57**
			After	20.5	1.8		
3	Systolic blood pressure	Routine care	Before	161.9	16.15	1.1	0.97
			After	160.8	17.4		
		Cryotherapy	Before	160.2	15.6	3.8	3.6**
			After	157	15.8		
4	Diastolic blood pressure	Routine care	Before	90.5	10.4	2.3	2.5*
			After	88.2	10.7		
		Cryotherapy	Before	94.4	7.5	7.2	6.4***
			After	87.2	6.5		

*** Significance at 0.001 level
** Significance at 0.01 level
* Significance at 0.05 level

The table 4.2.3 reveals that, the analysis on the effect of cryotherapy on physiological parameters among patients undergoing hemodialysis in Group I. Findings show that, the mean difference in pulse rate was 1.7 and 4.2 before and after routine care and cryotherapy respectively. The calculated ‘t’ value was 8.5 and 10.5 before and after routine care and cryotherapy respectively which were both found to be highly significant at 0.001 level.

The mean difference in respiratory rate was 0.4 and 0.54 before and after routine care and cryotherapy respectively. The calculated ‘t’ value was 4 before and after routine care which was found to be highly significant at 0.001 whereas ‘t’ value was 3.57 before and after cryotherapy which was found to be significant at 0.01 level.

The mean difference in systolic blood pressure was 1.1 and 3.8 before and after routine care and cryotherapy respectively. The calculated ‘t’ value was 3.6 before and after cryotherapy which was found to be significant at 0.01 level. The ‘t’ value was 0.97 before and after routine care which was lower than the table (2.1) value. Hence it was not significant.

The mean difference in the diastolic blood pressure was 2.3 and 7.2 before and after routine care and cryotherapy respectively. The calculated ‘t’ value was 2.5 before and after routine care which was found to be significant at 0.05 whereas ‘t’ value was 6.4 before and after cryotherapy which was found to be highly significant at 0.001 level.

Table 4.2.4

Analysis on the effect of cryotherapy on physiological parameters among Patients undergoing Hemodialysis in Group II

n=19

S. No	Physiological parameters	Study group	Observations	Mean	SD	Mean difference	Calculated 't' value
1	Pulse rate	Cryotherapy	Before	82.2	12.4	4.4	5.2***
			After	77.8	12.3		
		Routine care	Before	83.8	11.2	2.3	6.13***
			After	81.5	10.8		
2	Respiratory rate	Cryotherapy	Before	22.6	2.6	0.7	4.63***
			After	21.9	2.07		
		Routine care	Before	24.05	2.98	0.55	3.1**
			After	23.5	3.07		
3	Systolic blood pressure	Cryotherapy	Before	158.16	14.8	4.26	5.25**
			After	153.9	15.3		
		Routine care	Before	162.9	15.4	0.9	1.08
			After	162	15.3		
4	Diastolic blood pressure	Cryotherapy	Before	88.8	7.08	3.4	2.64*
			After	85.4	6.7		
		Routine care	Before	95.9	6.4	3.1	4.8***
			After	92.8	6.9		

*** Significance at 0.001 level
** Significance at 0.01 level
* Significance at 0.05 level

The table 4.2.4. states the analysis on the effect of cryotherapy on physiological parameters among patients undergoing hemodialysis in Group II. Findings show that, the mean difference in the pulse rate was 4.4 and 2.3 before and after cryotherapy and routine care respectively. The calculated 't' value was 5.2 and 6.13 before and after cryotherapy and routine care respectively, which were both found to be highly significant at 0.001 level.

The mean difference in respiratory rate was 0.7 and 0.55 before and after cryotherapy and routine care respectively. The calculated 't' value was 4.63 before and after cryotherapy which was found to be highly significant at 0.001 whereas, 't' value was 3.1 before and after routine care which was found to be significant at 0.01 level.

The mean difference in the systolic blood pressure was 4.26 and 0.9 before and after cryotherapy and routine care respectively. The calculated 't' value was 5.25 before and after cryotherapy which found to be significant at 0.001 level. The 't' value was 1.08 before and after routine care which was lower than the table (2.1) value. Hence it was not significant.

The mean difference in the diastolic blood pressure was 3.4 and 3.1 before and after cryotherapy and routine care respectively. The calculated 't' value was 2.64 before and after cryotherapy which was found to be significant at 0.05 whereas 't' value was 4.8 before and after routine care which was found to be highly significant at 0.001 level.

Section III

Assessment on level of arteriovenous fistula puncture related pain among patients undergoing hemodialysis.

This section deals with the analysis and interpretation of the pain among patients undergoing hemodialysis before and after cryotherapy. The level of objective pain assessment was done using Modified Abbey pain scale and subjective pain assessment was done using Numerical Pain Rating scale. Collected data were analyzed using descriptive statistics and presented under the following headings.

- Assessment on level of arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment scale among patients undergoing hemodialysis.
- Assessment on level of arteriovenous fistula puncture related pain using Numerical subjective Pain Rating scale among patients undergoing hemodialysis.

Table 4.3.1

Assessment on level of arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment scale among patients undergoing hemodialysis in Group I and II

Level of Pain	Group I (n=19)				Group II (n=19)			
	Routine care		cryotherapy		cryotherapy		Routine care	
	Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)
No pain (0-3)	3	15.79	18	94.74	19	100	6	31.58
Mild (4-6)	15	78.95	1	5.26	0	0	13	68.42
Moderate (7-9)	1	5.26	0	0	0	0	0	0

Table 4.3.1 represents the level of objective pain assessed during interventions in Group I and II. In Group I, 3 (15.79%) patients had no pain, 15 (78.95%) patients had mild pain and one patient had moderate pain after routine care. Majority of them, 18 (94.74%) had no pain after cryotherapy.

In group II, 6 (31.58%) patients had no pain and 13 (68.42%) patients had mild pain after routine care. None of the patients had no pain after cryotherapy.

Table 4.3.2

Assessment on level of arteriovenous fistula puncture related pain using Numerical Rating subjective pain assessment scale among patients undergoing hemodialysis in Group I and II

Level of Pain	Group I (n=19)				Group II (n=19)			
	Routine care		Cryotherapy		Cryotherapy		Routine care	
	Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)
No pain (0)	0	0	2	10.53	0	0	0	0
Mild (1-3)	2	10.53	14	73.68	16	84.21	0	0
Moderate (4-6)	7	36.84	2	10.53	3	15.79	10	52.63
Severe (7-10)	10	52.63	1	5.26	0	0	9	47.37

Table 4.3.2 describes the level of subjective pain assessed after intervention in Group I and II. In Group I, majority 10 (52.63%) of patients had severe pain, 7 (36.84%) had moderate pain and 2 (10.53%) had mild pain after routine care. Majority 14 (73.68%) of patients had mild pain, 2 (10.53%) had moderate and no pain respectively and 1 (5.26%) had severe pain after cryotherapy.

In group II, majority of 16 (84.21%) patients had mild pain and 3 (15.79%) had moderate pain after cryotherapy. Majority, 10 (52.63%) of patients had moderate pain and 9 (47.37%) of them had severe pain after routine care.

Table 4.3.3

Mean and standard deviation of objective and subjective pain among Group I and II patients undergoing hemodialysis

	Group I (n=19)				Group II (n=19)			
	Routine care		Cryotherapy		Cryotherapy		Routine care	
	Objective pain	Subjective pain	Objective pain	Subjective pain	Objective pain	Subjective pain	Objective pain	Subjective pain
Mean	4.03	6.07	1.83	2.04	1.76	2.08	3.82	6
SD	1.31	1.76	0.84	1.58	0.64	0.89	0.88	0.94

The above table 4.3.3 projects that, the mean score of objective pain during routine care and cryotherapy was 4.03 and 1.83 with standard deviation was 1.31 and 0.84 among patients in Group I. Whereas, the mean score of objective pain during cryotherapy and routine care was 1.76 and 3.82 with standard deviation was 0.64 and 0.88 among patients in Group II.

The mean score of subjective pain after routine care and cryotherapy was 6.07 and 2.04 with standard deviation was 1.76 and 1.58 among patient in Group I. Whereas, the mean score of subjective pain after cryotherapy and routine care was 2.08 and 6 with standard deviation was 0.89 and 0.94 among patients in Group II.

Section IV

Effect of cryotherapy on arteriovenous fistula puncture related pain among patients undergoing hemodialysis.

This section deals with the analysis and interpretation of the effect of cryotherapy on arteriovenous fistula puncture related pain using Numerical subjective pain assessment rating scale and Modified Abbey objective pain assessment among patients undergoing hemodialysis.

Table 4.4.1

Analysis on effect of cryotherapy on arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment scale among patients undergoing hemodialysis in exclusive Group I and II

S. No	Groups	Observation	Mean	SD	Mean difference	Calculated 't' value
1	Group I	Routine care	4.03	1.31	2.2	5.8***
		Cryotherapy	1.83	0.84		
2	Group II	Cryotherapy	1.76	0.64	2.06	7.9***
		Routine care	3.82	0.88		

*** Significance at 0.001 level

Student 't' test was used to analyze the effect of cryotherapy on arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment scale among patients undergoing hemodialysis in exclusive Group I and II.

Group I analysis shows that, the mean score of routine care and cryotherapy was 4.03 and 1.83 with standard deviation was 1.31 and 0.84. The mean difference was 2.2. The calculated 't' value 5.8 was greater than the table value 3.92 at 0.001 level of significance.

Group II analysis shows that, the mean of cryotherapy and routine care was 1.76 and 3.82 with standard deviation was 0.64 and 0.88. The mean difference was 2.06. The calculated 't' value 7.9 greater than the table value 3.92 at 0.001 level of significance.

Hence the research hypothesis **$H_0$1**: "There is no significant difference in the arteriovenous fistula puncture related pain between interventions" was rejected.

Table 4.4.2

Analysis on effect of cryotherapy on arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment Scale among patients undergoing hemodialysis

S. No	Groups	Observation	Mean	SD	Mean difference	Calculated 't' value
1	Group I & II	Routine care	4.03	1.06	0.21	0.55
			3.82	1.26		
2	Group I & II	Cryotherapy	1.83	0.83	0.07	0.27
			1.76	0.96		

Student 't' test was used to compare the level of arteriovenous fistula puncture related pain after routine care and cryotherapy among patients undergoing hemodialysis between groups.

The means score of Group I and II was 4.03 and 3.82 with standard deviation was 1.06 and 1.26 after routine care. The mean difference was 0.21. The calculated 't' value 0.55 was lesser than the table value 2.10 at 0.05 level of significance. After cryotherapy mean score of Group I and II was 1.83 and 1.76 with standard deviation was 0.83 and 0.96 after cryotherapy. The mean difference was 0.07. The calculated 't' value 0.27 was lesser than the table value 2.10 at 0.05 level of significance.

Hence the research hypothesis **$H_0$2:** "There is no significant difference in the arteriovenous fistula puncture related pain between groups" was accepted.

Table 4.4.3

Analysis on effect of cryotherapy on arteriovenous fistula puncture related pain using Numerical subjective pain assessment scale among patients undergoing hemodialysis in exclusive Group I and II

S. No	Groups	Observation	Mean	SD	Mean difference	Calculated 't' value
1	Group I	Routine care	6.07	1.76	4.03	6.95***
		Cryotherapy	2.04	1.58		
2	Group II	Cryotherapy	2.08	0.89	3.92	12.65***
		Routine care	6	0.94		

***Significance at 0.001 level

Student 't' test was used to analysis on effect of cryotherapy on arteriovenous fistula puncture related pain using numerical subjective pain assessment scale among patients undergoing hemodialysis in exclusive Group I and II.

In Group I analysis shows that, the mean score of routine care and cryotherapy was 6.07 and 2.04 with the mean difference of 4.03. The standard deviation was 1.76 and 1.58. The calculated 't' value 6.95 greater than the table value 3.92 at 0.001 level of significance.

In Group II analysis shows that, the mean score of cryotherapy and routine care was 6 and 2.08 with the mean difference of 3.95. The calculated standard deviation was 0.94 and 0.89. The calculated 't' value 12.65 greater than the table value 3.92 at 0.001 level of significance.

Hence the research hypothesis H_0**1:** "There is no significant difference in the arteriovenous fistula puncture related pain between groups" was rejected.

Table 4.4.4

Analysis on effect of cryotherapy on arteriovenous fistula puncture related pain using Numerical subjective pain assessment Rating scale among patients undergoing hemodialysis

S. No	Groups	Observation	Mean	SD	Mean difference	Calculated 't' value
1	Group I & II	Routine care	6.07	1.76	0.07	1.5
			6	0.94		
2	Group I & II	Cryotherapy	2.04	1.58	0.04	0.09
			2.08	0.89		

Student 't' test was used to compare the level of arteriovenous fistula puncture related pain after routine care and cryotherapy among patients undergoing hemodialysis between groups.

The means score of Group I and II was 6.07 and 6 with the mean difference of 0.07 after routine care. The calculated standard deviation was 1.76 and 0.94. The calculated 't' value 1.5 lesser than the table value 2.10 at 0.05 level of significance. Mean score of Group I and II was 2.04 and 2.08 with the mean difference of 0.04 after cryotherapy. The calculated standard deviation was 1.58 and 0.89. The calculated 't' value 0.09 lesser than the table value 2.10 at 0.05 level of significance.

Hence the research hypothesis **$H_0$2:** "There is no significant difference in the arteriovenous fistula puncture related pain between groups" was accepted.

Section V

Correlation between the arteriovenous fistula puncture related pain observed using modified Abbey pain scale and numerical pain rating scale

In this present study the arteriovenous fistula puncture related pain was observed using two different tools. Hence, an attempt was made to analyses the correlation between the Modified Abbey objective pain scale and Numerical subjective pain Rating scale among patient undergoing hemodialysis.

Table 4.5.1

Correlation between the arteriovenous fistula puncture related pain observed using Modified Abbey pain scale and Numerical Pain Rating scale

S. No	Interventions	Pain Scale	Correlation Coefficient 'r' Value
1	Cryotherapy	Modified Abbey objective pain scale	0.6***
		Numerical subjective pain rating scale	
2	Routine care	Modified Abbey objective pain scale	0.7***
		Numerical subjective pain rating scale	

*** P<0.001; Table value 0.490

Table 4.5.1 shows that, the calculated 'r' value between Modified Abbey objective pain scale and Numerical subjective pain rating scale among recipients of cryotherapy was 0.6.

The calculated 'r' value between Modified Abbey objective pain scale and Numerical subjective pain rating scale among the recipients of routine care was 0.7.

The results revealed that, there was a highly significant positive correlation between subjective and objective pain scores after cryotherapy and routine care.

Hence, the null hypothesis **$H_0$3**: There is no significant correlation between the Modified Abbey pain scale and Numerical Pain Rating scale between groups was rejected. The result showed that the subjective pain score perceived by the patients and the objective pain score observed by the researcher was positively correlated.

RESULTS AND DISCUSSION

This chapter deals with the interpretation of the results and discussion of the findings. The aim of the study is to assess the effect of cryotherapy on arteriovenous puncture related pain among patients undergoing hemodialysis. The study was conducted at Dialysis unit, Sri Ramakrishna Hospital, Coimbatore. Repeated measures cross over design were used. 38 patients were selected according to the inclusion criteria. The samples were assigned as group I and group II. Routine care was given first in the Group I and cryotherapy was given first in the Group II which was alternated in the subsequent dialysis for two weeks. The researcher administered cryotherapy for 12 minutes for patients. The level of arteriovenous puncture related pain was assessed during routine care or cryotherapy by using Modified Abbey pain scale for objective pain assessment and Numerical Pain Rating Scale for subjective pain assessment for patients undergoing hemodialysis.

The data was analysed and the findings were discussed based on the objectives of the study.

5.1 Findings Related to Demographic Profile

In the present study, 38 patients were included majority of 16 (42.10%) patients were between the age group of 61-70 years, 13 (34.21%) patients were between the age group of 51-60 years, 5 (13.16%) patients were between the age group of 31- 40 years and 4 (10.53%) patients were between the age group of 41-50years. A similar study was conducted by Aghajanloo, Ghafourifard, Haririan and Gheydari (2016) to comparison of the effects of cryotherapy and placebo on

reducing the pain of arteriovenous fistula cannulation among hemodialysis patients. It concludes that mean age of the patients was above 50 years. According to the literature, advanced age is a major risk factor for the incidence of chronic renal failure

Gender of the participants states that, majority 29 (76.32%) of patients were males and 9 (23.68%) were females. A similar study was conducted by Davtalab, Naji and Shahidi (2016) to comparing the effects of Valsalva maneuver and ice massage at Hoku point methods on pain intensity within the needle insertion to the arteriovenous fistula (AVF) for patients undergoing hemodialysis in the selected hospitals in Isfahan. The result says that the most of the participants were men (58.6%).

The data based on their educational status. The findings show that, majority 14 (36.84%) of patients were graduates, 7 (18.42%) patients studied up to higher secondary education, 4 (10.53%) patients had primary school education and higher school education respectively, 3 (7.89%) patients studied up to middle school education and 6 (15.79%) patients were illiterates.

Occupational status of the participants states that, a majority of 30 (78.95%) patients were unemployed and 8 (21.05%) patients were employed. A similar study conducted by Fareed, Abd El-Hay and El-Shikh to Cutaneous Stimulation: its Effect on pain Relieving among Hemodialysis Patients. This study revealed regarding occupation, more than one third of them were either house wife or not working at all (36.5% and 38.5% respectively).

Family monthly income and result shows that a majority of 24 (63.16%) patients have a monthly income above ₹ 15,000, 14 (36.84%) patients have the monthly income between ₹ 10,001 – 15,000.

The patients based on the duration of diagnosis of renal failure notify that majority of 24 (63.16%) patients were diagnosed with renal failure between 1-10years, 13 (34.21%) patients were less than one years and one patient was diagnosed with renal failure between 11-20 years.

The participants duration of hemodialysis report that out of 38 patients, 21 (55.26%) patients were on hemodialysis for 1 to 5 years, and 17 (44.74%) patients were on dialysis for less than one year.

The duration of present arteriovenous fistula shows that majority of 13 (34.21%) patients were on arteriovenous fistula for 1-6 months, 10 (26.32%) patients were for 19-24months, 8 (21.05%) and 7(18.42%) patients were on arteriovenous fistula for 7-12 months and 13-18 months respectively.

The presence of associated illness among patients undergoing hemodialysis report that majority of 37 (97.37%) patients had associated illnesses like diabetes mellitus, Hypertension, Hepatitis, Anaemia and cardiac problems along with renal failure.

Number of hemodialysis cycles in a week reveals that 33 (86.84%) patients were on hemodialysis cycles twice a week and 5 (13.16%) patients were on hemodialysis for thrice a week. A similar study conducted by Golda, Revathi, Subhashini, Mathew and Indira (2016) to assess the effectiveness of cold

application on pre procedure (AV fistula puncture) pain among hemodialysis patients in tertiary care hospital, Nellore. The result says that in experimental group 80% and control group 60% of participants had two cycles a week.

5.2 Effect of cryotherapy on physiological parameters among Patients undergoing Hemodialysis in Group I and II

The data explains that there is a significant difference in pulse rate, respiratory rate and diastolic blood pressure of before and after routine care and cryotherapy respectively and there is a significant difference in systolic blood pressure of before and after cryotherapy among patients undergoing hemodialysis in Group I and II. A similar study was conducted by Fareed, Abd El-Hay and El-shikh (2014) to effect of cutaneous stimulation on pain relieving at AV fistula puncture site among hemodialysis patients. The result shows that there is a significant difference ($P<0.001$) in physiological parameters of before and after cutaneous stimulation during first and second visit.

5.3 Assessment on level of arteriovenous fistula puncture related pain among patients undergoing hemodialysis

The study represents the level of objective pain assessed during interventions in Group I, 3(15.79%) patients had pain, 15 (78.95%) had mild pain and one patient had moderate pain after routine care. Majority of them, 18 (94.74%) had no pain after cryotherapy. In Group II, 6 (31.58%) patients had no pain and 13 (68.42%) had mild pain after routine care. None of the patients had no pain after cryotherapy. The level of subjective pain assessed after intervention in Group I, majority 10 (52.63%) of patients had severe

pain, 7 (36.84%) had moderate pain and 2 (10.53%) had mild pain after routine care. Majority 14 (73.68%) of patients had mild pain,2 (10.53%) had moderate and no pain respectively and 1 (5.26%) had severe pain after cryotherapy. In Group II, majority of 16 (84.21%) patients had mild pain and 3 (15.79%) had moderate pain after cryotherapy. Majority, 10 (52.63%) of patients had moderate pain and 9 (47.37%) of them had severe pain after routine care.

A similar study was conducted by Pachori (2017) Comparison the level of subjective pain score between experimental and control group indicates that in control group, 13.3% of the patients are having mild pain, 36.7% are having moderate pain and 50% of the patients are having severe pain. In experimental group 33.3% of the patients are having mild pain, 46.7% are having moderate pain and 20.0% of the patients are having severe pain. This difference is statistically significant (P=0.03). Comparison the level of pain behavior scores between experimental and control group indicates that in control group, 13.3% of the patients are having mild pain, 46.7% are having moderate pain and 40% of the patients are having severe pain. In experimental group 36.7% of the patients are having mild pain, 46.7% are having moderate pain and 16.7% of the patients are having severe pain.

5.4 Effect of cryotherapy on arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment scale among patients undergoing hemodialysis in exclusive Group I and II

Student ‘t’ test was used to analyze the effect of cryotherapy on arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment scale among patients undergoing hemodialysis in exclusive Group I

and II. Group I analysis shows that, the mean score of routine care and cryotherapy was 4.03 and 1.83 with standard deviation was 1.31 and 0.84. The mean difference was 2.2. The calculated 't' value 5.8 was greater than the table value 3.92 at 0.001 level of significance. Group II analysis shows that, the mean of cryotherapy and routine care was 1.76 and 3.82 with standard deviation was 0.64 and 0.88. The mean difference was 2.06. The calculated 't' value 7.9 greater than the table value 3.92 at 0.001 level of significance. Hence the research hypothesis **$H_0$1**: "There is no significant difference in the arteriovenous fistula puncture related pain between interventions" was rejected.

A similar study conducted by Davtalab, Naji and Shahidi (2016) to comparing the effects of Valsalva maneuver and ice massage at Hoku point methods on pain intensity within the needle insertion to the arteriovenous fistula (AVF) for patients undergoing hemodialysis in the selected hospitals in Isfahan. The results of this study shows that, the averages of objective and subjective pain scores before intervention in Valsalva maneuver group and ice massage group are 2.9±0.7 and 5±1.6 and 3.2±1.1 and 4.9±1.5 respectively and also after intervention are 2.4±0.7 and 4.1±1.7 in Valsalva maneuver group and 2.8±1.1 and 4.2±1.3 in ice massage group. The result showed that the averages of objective and subjective pain scores after intervention is decreased significantly ($P<0.001$) compared to before intervention, in both Valsalva maneuver and ice massage groups.

5.5 Analysis on effect of cryotherapy on arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment Scale among patients undergoing hemodialysis

Analysis show that, the mean score of Group I and II was 4.03 and 3.82 with standard deviation was 1.06 and 1.26 after routine care. The mean difference was 0.21. The calculated 't' value 0.55 was lesser than the table value 2.10 at 0.05 level of significance. The mean score was 1.83 and 1.76 with standard deviation was 0.83 and 0.96 after cryotherapy. The mean difference was 0.07. The calculated 't' value 0.27 was lesser than the table value 2.10 at 0.05 level of significance. Hence the research hypothesis **$H_0$2:** "There is no significant difference in the arteriovenous fistula puncture related pain between groups" was accepted.

5.6 Analysis on effect of cryotherapy on arteriovenous fistula puncture related pain using Numerical subjective pain assessment rating scale among patients undergoing hemodialysis in exclusive Group I and II

In Group I analysis shows that, the mean score of routine care and cryotherapy was 6.07 and 2.04 with the mean difference of 4.03. The standard deviation was 1.76 and 1.58. The calculated 't' value 6.95 greater than the table value 3.92 at 0.001 level of significance. In Group II analysis shows that, the mean score of cryotherapy and routine care was 6 and 2.08 with the mean difference of 3.95. The calculated standard deviation was 0.94 and 0.89. The calculated 't' value 12.65 greater than the table value 3.92 at 0.001 level of significance. Hence the research hypothesis **$H_0$1:** "There is no significant difference in the arteriovenous fistula puncture related pain between groups" was rejected.

A similar study was conducted by Patidar (2015) to assess the effectiveness of cryotherapy on pain during arteriovenous fistula puncture among hemodialysis patients. This study revealed that the subjective assessment of pain level before and after cryotherapy mean score was 4.01 and 2.98 and standard deviation was 1.31 and 0.59. The calculated 't' value 2.75 greater than the table value 1.96 at 0.05 level of significance. It indicates that the cryotherapy is significantly effective in improving the level of pain among patients undergoing hemodialysis with AV fistula.

5.7 Analysis on effect of cryotherapy on arteriovenous fistula puncture related pain using Numerical subjective pain assessment rating scale among patients undergoing hemodialysis

Analysis show that, the mean score of Group I and II was 6.07 and 6 with the mean difference of 0.07 after routine care. The calculated standard deviation was 1.76 and 0.94. The calculated 't' value 1.5 lesser than the table value 2.10 at 0.05 level of significance. The mean score of Group I and II was 2.04 and 2.08 with the mean difference of 0.04 after cryotherapy. The calculated standard deviation was 1.58 and 0.89. The calculated 't' value 0.09 lesser than the table value 2.10 at 0.05 level of significance. Hence the research hypothesis **$H_0$2:** "There is no significant difference in the arteriovenous fistula puncture related pain between groups" was accepted.

5.8 Correlation between the arteriovenous fistula puncture related pain observed using Modified Abbey pain scale and Numerical Pain Rating scale

The study analysis shows that, calculated 'r' value between Modified Abbey objective pain scale and Numerical subjective pain rating scale among cryotherapy was 0.6. Likewise the calculated 'r' value between Modified Abbey objective pain scale and Numerical subjective pain rating scale among the routine care was 0.7. This shows there is a positive correlation between subjective and objective pain scores. Hence, the null hypothesis **$H_0$3** "There is no significance correlation between the Modified Abbey pain scale and Numerical Pain Rating scale between groups" was rejected.

SUMMARY AND CONCLUSION

This chapter deals with the findings, limitations, suggestions for the study and implications in the field of nursing education, practice, administration and nursing research. The study was conducted to identify the effect of cryotherapy on arteriovenous puncture related pain among patients undergoing hemodialysis at selected hospital, Coimbatore.

Repeated measures cross over design was adopted in this study. Modified widen bach's helping art of clinical nursing theory was used as a conceptual framework for the study. The study was conducted in the dialysis unit of Sri Ramakrishna Hospital, Coimbatore. Modified Abbey pain scale was developed by Abbey J. et.al (2002) for objective pain assessment during arteriovenous fistula puncture and Numerical pain rating scale was developed by the McCaffery and Beebe for subjective pain assessment among patients undergoing hemodialysis. 38 patients were selected according to the inclusion criteria. All the samples received cryotherapy and routine care in alternative visits. The researcher administered the cryotherapy for 12 minutes to the patients. The level of arteriovenous puncture related pain was assessed during and after intervention by using Numerical Pain Rating Scale for subjective pain assessment and Modified Abbey Pain Scale for objective pain assessment for patients undergoing hemodialysis both experimental and control group.

6.1 Major Findings of the Study

6.1.1 Age of patients undergoing hemodialysis revealed that, majority of 16 (42.10%) patients were between the age group of 61-70years, 13 (34.21%) patients were between the age group of 51-60years.

6.1.2 Age of patients undergoing hemodialysis revealed that, majority of 29 (76.32%) patients were males.

6.1.3 Educational status of patients undergoing hemodialysis revealed that, majority of 14 (36.84%) patients were graduate.

6.1.4 Occupational status of patients undergoing hemodialysis revealed that, majority of 30 (78.95%) patients were unemployed.

6.1.5 Duration of diagnosis of renal failure of patients undergoing hemodialysis revealed that, majority of 24 (63.16%) patients were diagnosed with renal failure between 1-10years.

6.1.6 Presence of associated illness among patients undergoing hemodialysis revealed that, majority of 37 (97.37%) patients had associated illnesses along with renal failure such as diabetes mellitus, Hypertension, Hepatitis, Anaemia and cardiac problems.

6.1.7 Number of hemodialysis cycles among patients undergoing hemodialysis revealed that, majority of 33 (86.84%) patients were on hemodialysis cycles twice a week.

6.1.8 There is a significant difference in pulse rate, respiratory rate and diastolic blood pressure before and after routine care and cryotherapy in Group I

and II and there is a significant difference in the systolic blood pressure before and after cryotherapy among patients undergoing hemodialysis in Group I and II.

6.1.9 Level of objective pain assessed based on the Modified Abbey objective pain assessment scale during interventions in Group I and II. In Group I, 3 (15.79%) patients had no pain, 15 (78.95%) patients had mild pain and one patient had moderate pain after routine care. The majority of 18 (94.74%) had no pain after cryotherapy. In Group II, 6 (31.58%) patients had no pain, 13 (68.42%) patients had mild pain after routine care. None of the patients had no pain after cryotherapy.

6.1.10 Level of subjective pain assessed after intervention in Group I and II. In Group I, majority 10 (52.63%) of patients had severe pain, 7 (36.84%) had moderate pain and 2 (10.53%) had mild pain after routine care. Majority 14 (73.68%) of patients had mild pain, 2 (10.53%) had moderate and no pain respectively and 1 (5.26%) had severe pain after cryotherapy. In Group II, majority of 16 (84.21%) patients had mild pain and 3 (15.79%) had moderate pain after cryotherapy. Majority, 10 (52.63%) of patients had moderate pain and 9 (47.37%) of them had severe pain after routine care.

6.1.11 Effect of cryotherapy on arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment scale among patients undergoing hemodialysis in exclusive Group I and II. Analysis among Group I show that, the mean score of routine care and cryotherapy was 4.03 and 1.83 with standard deviation was 1.31 and 0.84. The mean

difference was 2.2. The calculated 't' value 5.8 was greater than the table value 3.92 at 0.001 level of significance. Analysis among Group II show that, the mean of cryotherapy and routine care was 1.76 and 3.82 with standard deviation was 0.64 and 0.88. The mean difference was 2.06. The calculated 't' value 7.9 greater than the table value 3.92 at 0.001 level of significance. Hence the research hypothesis **$H_0$1**: "There is no significant difference in the arteriovenous fistula puncture related pain between interventions" was rejected.

6.1.12 Level of arteriovenous fistula puncture related pain after routine care and cryotherapy among patients undergoing hemodialysis between groups. Analysis show that, the mean score of Group I and II was 4.03 and 3.82 with standard deviation was 1.06 and 1.26 after routine care. The mean difference was 0.21. The calculated 't' value 0.55 was lesser than the table value 2.10 at 0.05 level of significance. The mean score was 1.83 and 1.76 with standard deviation was 0.83 and 0.96 after cryotherapy. The mean difference was 0.07. The calculated 't' value 0.27 was lesser than the table value 2.10 at 0.05 level of significance. Hence the research hypothesis **$H_0$2:** "There is no significant difference in the arteriovenous fistula puncture related pain between groups" was accepted.

6.1.13 Effect of cryotherapy on arteriovenous fistula puncture related pain using Numerical subjective pain assessment rating scale among patients undergoing hemodialysis in exclusive Group I and II. Analysis among Group I show that, the mean score of routine care and cryotherapy was 6.07 and 2.04 with the mean difference of 4.03. The standard deviation was 1.76 and 1.58. The calculated 't' value 6.95 greater than the table

value 3.92 at 0.001 level of significance. Analysis among Group II show that, the mean score of cryotherapy and routine care was 6 and 2.08 with the mean difference of 3.95. The calculated standard deviation was 0.94 and 0.89. The calculated 't' value 12.65 greater than the table value 3.92 at 0.001 level of significance. Hence the research hypothesis H_0**1:** "There is no significant difference in the arteriovenous fistula puncture related pain between groups" was rejected.

6.1.14 Level of arteriovenous fistula puncture related pain using Numerical subjective pain assessment rating scale after routine care among undergoing hemodialysis between Group I and II. Analysis shows that, the mean score of Group I and II was 6.07 and 6 with the mean difference of 0.07 after routine care. The calculated standard deviation was 1.76 and 0.94. The calculated 't' value 1.5 lesser than the table value 2.10 at 0.05 level of significance. The mean score of Group I and II was 2.04 and 2.08 with the mean difference of 0.04 after cryotherapy. The calculated standard deviation was 1.58 and 0.89. The calculated 't' value 0.09 lesser than the table value 2.10 at 0.05 level of significance. Hence the research hypothesis **$H_0$2:** "There is no significant difference in the arteriovenous fistula puncture related pain between groups" was accepted.

6.1.15 The calculated 'r' value between Modified Abbey objective pain scale and Numerical subjective pain rating scale among cryotherapy was 0.6. Likewise the calculated 'r' value between Modified Abbey objective pain scale and Numerical subjective pain rating scale among the routine care was 0.7. It revealed that there was a highly significant positive correlation between subjective and objective pain scores. Hence, the null hypothesis

$H_0$3: There is no significant correlation between the Modified Abbey pain scale and Numerical Pain Rating scale between groups was rejected. The result showed that the subjective pain score perceived by the patients and the objective pain score observed by the researcher was positively correlated.

6.2 Limitation

6.2.1 Sample size of the study was small which limits the generalization of the study findings.

6.2.2 The duration of the data collection period was short.

6.3 Recommendations

6.3.1 Replication of the study could be done with larger samples to validate and generalize the findings.

6.3.2 Staff nurses have to be trained to implement cryotherapy during hemodialysis to reduce the level of arteriovenous fistula puncture related pain.

6.3.3 Cryotherapy can be performed by patients undergoing hemodialysis.

6.3.4 It can be implemented to acute and chronic centres for renal patients.

6.4 Nursing Implication

6.4.1 Nursing Education

Cryotherapy is found to be effective in reducing the level of puncture related pain among patients undergoing hemodialysis. Nurse educators need to have adequate knowledge and awareness on cryotherapy. The nurse educator must motivate the staff nurses and nursing students in performing it as daily routine.

The importance of cryotherapy can be taught to patients, student nurses and staff nurses by using audio-visual aids. It can be emphasized and included in the nursing curriculum. Cryotherapy is simple and can be taught to all para medical professionals.

6.4.2 Nursing Administration

The nurse administrator can formulate policies regarding cryotherapy and implement in the entire hemodialysis units. A check list can be prepared and practiced by health care personnel. Periodical surveillance can be helpful on reduction of pain related arteriovenous fistula puncture among patients undergoing hemodialysis. It can be formulated as a routine care while delivering hemodialysis. The nurse administrator can create a manual regarding the details of cryotherapy. Thereby nurses can update the knowledge about various therapies which are useful for clinical practice through in-service and continuing education.

6.4.3 Nursing Practice

Cryotherapy before arteriovenous fistula puncture related pain during hemodialysis is less time consuming and effective in reducing pain among patients undergoing hemodialysis. Nurses working in hemodialysis unit should be trained to focus on the cryotherapy. Nurses must update their knowledge regarding cryotherapy. Client with arteriovenous fistula puncture related pain can be provided cryotherapy and encouraged to practice in each cycle of hemodialysis. Nursing assessment of arteriovenous fistula puncture related pain is important in the care of patients receiving dialysis in order to improve their quality of life. Nurses working in various settings should be trained to focus on this intervention among the people undergoing hemodialysis.

6.4.4 Nursing Research

It can be used as an evidence based practice for reducing arteriovenous fistula puncture related pain. Similar studies can be undertaken for assessing the arteriovenous fistula puncture related pain among patients in different settings. Further research is necessary to determine the ideal type, amount, timing and frequency of cryotherapy for patients on hemodialysis for better outcome.

6.5 Conclusion

Hemodialysis is the treatment of choice for the majority of patients with chronic renal failure. Although hemodialysis is a lifesaving therapy, it is not without unpleasant side effects. The symptoms experienced by patients on hemodialysis makes the patient extremely inactive. Their functional capacity and quality of life are reduced compared to healthy individuals.

Arteriovenous Fistula is one of the inevitable elements in the take care of hemodialysis patients. Quality of dialysis depends on its good functioning. So the different complications which result from its use like pain during cannulation influence directly life's quality of hemodialysis patients. Pain of AVF puncture is a real problem for patients.

Cryotherapy on managing the pain at the AVF puncture site among patients undergoing maintenance hemodialysis. Cryotherapy was associated with significant decreases in both the subjective and objective parameters of pain measurement. Cryotherapy or ice massage can effectively reduce the sensation of pain from venipuncture among patient with AVF and undergoing maintenance HD. This effect was demonstrated through subjective and objective pain assessments. Cryotherapy was a safety, simple and non-pharmacological management used for pain management and it help to improve the quality of hemodialysis patients.

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SRI RAMAKRISHNA HOSPITAL ETHICAL COMMITTEE

395, SAROJINI NAIDU ROAD, SIDHAPUDUR, COIMBATORE - 641 044.
Phone : 0422 - 4500000, 4500201, Grams :"RAMHOSP" Fax : 0422-2240521
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Ethics Committee Registration No. ECR/690/Inst/TN/2014

SRH/EC.11-17/2017-18

1st September 2017

ETHICAL CLEARANCE CERTIFICATE

Project Title:"Effect of Cryotherapy on Arterriovenous Fistula Puncture Related Pain among Patients Undergoing Hemodialysis at Selected Hospital, Coimbatore".

Researcher: Ms.J.Berin Sheeba,
MSc Nursing 1st year,
Medical Surgical Nursing,
College of Nursing, SRIPMS,
Coimbatore.

The following members of the ethics committee were present at the meeting held on 26.08.2017 at 11.00am at New Auditorium, Sri Ramakrishna Hospital Campus, Coimbatore.

SI NO	Members Name	Qualification	Designation	Address	Affiliation To the Institution Yes/NO
1.	Dr.P.Murali	M.Sc.,Ph.D., D.Sc	Scientist Mg. Director & CEO	Mg.Director & CEO Evolve Biotech Pvt.Ltd., 401 – 405, 4th floor Ticel Bio park Ltd, Taramani, Chennai - 13	No
2.	Dr.P.Sukumaran	MS., M.Ch., FIACS	Scientific / EC Member Secretary Dean	Dean Sri Ramakrishna Hospital, 395, Sarojini Naidu Road, Sidhapudur, Coimbatore	Yes
3.	Dr.T.Mohan Kumar	MD.,D.Sc., AB.,DPPR., FCCP.,	Clinician	Sr.Consultant Pulmonologist Sri Ramakrishna Hospital, 395, Sarojini naidu Road, Sidhapudur, Coimbatore.	Yes
4.	Dr.P.R.Ramakrishnan	B.Com.,B.L.,	Legal Expert	Advocate No.2 Ramar Kovil Street, Ramnagar, Coimbatore.	No

Sri Ramakrishna Hospital

Medical Service : M/s. S.N.R. SONS CHARITABLE TRUST

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Ethics Committee Registration No. ECR/690/Inst/TN/2014

Ethics Committee Chairman

Dr. P. M. Murali, M.Sc.,Ph.D.,D.Sc.,

Ethics Committee Member Secretary

Dr. P. Sukumaran, MS.,M.Ch.,FIACS.,

Ethics Committee Members

Dr. MohanKumar T. MD.,AB.,D.Sc., DPPR.,FCCP.,
Clinician

Dr. R. Lalitha, DGO.,
Clinician

Dr. S. Rajagopal, M.Ch.,
Clinician

Dr. M. Rangasamy, B.E.,M.Sc.(Engg.)Ph.D.,
Lay Person

Dr. T.K. Ravi, M.Pharm.,Ph.D.,
Scientific Member

Dr. N. Paramasivan, MBBS., MD.,(Pharmacology)
Basic Medical Scientist

Mr. P. R. Ramakrishnan, B.Com.,B.L.,
Legal Expert

Mrs. Mythili Padmanabhan, M.Sc.,
Social Scientist

5.	Dr.R.Lalitha	DGO.,(OG)	Clinician	Sr.Consultant Gynecologist & HOD Sri Ramakrishna Hospital, 395, Sarojini naidu Road, Sidhapudur, Coimbatore.	Yes
6.	Dr.T.K.Ravi	M.Pharm Ph.D	Scientific Member	Principal Sri Ramakrishna College of pharmacy 395, Sarojini naidu Road, Sidhapudur, Coimbatore.	Yes
7.	Dr.N.Paramasivan	MBBS.,MD	Basic Medical Scientist	Prof.of pharmacology and HOD Sri Ramakrishna Dental College and Hospital, Coimbatore.	Yes
8.	Mrs.Mythili Padmanabhan	M.Sc., (Physiology)	Social Scientist	Corresponded Vriksha 5/14, 2nd street, G.G.Avenue Coimbatore	No

This is to certify that the research work entitled "Effect of Cryotherapy on Arterriovenous Fistula Puncture Related Pain among Patients Undergoing Hemodialysis at Selected Hospital, Coimbatore", placed before the Institutional Ethical Committee has been approved as there is no objection to do this research work.

This ethics committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report.

The Ethics Committee wishes her well in her research.

Yours Truly,

Member Secretary,
Institutional Human Ethics Committee,

Dr. P. SUKUMARAN, M.S.,M.Ch.,FIACS.,
Dean
SRI RAMAKRISHNA HOSPITAL,
395, Sarojini Naidu Road,
Sidhapudur, Coimbatore-641 044.

PERMISSION LETTER FOR CONDUCTING THE STUDY

From,

Ms. Berin sheeba .J,

M.Sc. Nursing 1st year,

College of Nursing, SRIPMS,

Coimbatore.

To,

The DEAN,

Sri Ramakrishna Hospital,

Coimbatore.

Through

The Principal,

College of Nursing, SRIPMS,

Coimbatore.

Respected Sir/Madam

Subject: Requesting permission to conducting the study

As a part of my curriculum requirement, I have undertaken the following study for my research **"EFFECT OF CRYOTHERAPY ON ARTERIOVENOUS FISTULA PUNCTURE RELATED PAIN AMONG PATIENTS UNDERGOING HEMODIALYSIS AT SRI RAMAKRISHNA HOSPITAL, COIMBATORE"**. I would like to conduct the above mentioned study in Hemodialysis unit of Sri Ramakrishna Hospital, Coimbatore. I kindly request you to grant me permission to conduct the study. I assure that I abide the rules and regulation of the institution and collected information from the participants will not be disclosed.

Thanking you,

Coimbatore,
28.08.2017.

Yours sincerely,

(J. Berin sheeba)

Copy to: Dr.CHEZHIYAN, Consultant Nephrologist

To permit

28/8/17
Dean

PRINCIPAL
College of Nursing
Sri Ramakrishna Institute of Paramedical Sciences
Coimbatore - 641 044

REQUISITION LETTER TO VALIDATE THE RESEARCH TOOL AND CONTENT

From,

Ms. Berin sheeba .J,

M.Sc. Nursing 1st year,

College of Nursing, SRIPMS,

Coimbatore.

To,

The Principal,
KMCH college of Nursing,
Coimbatore.

Through

The Principal,

College of Nursing, SRIPMS,

Coimbatore.

Respected Sir/Madam

Subject: Requesting permission to validate the research tool and content

I am Ms. Berin sheeba. J doing my 1st year MSc Nursing in College Of Nursing, Sri Ramakrishna Institute of Paramedical Science. As a part of my Nursing program, I have undertaken the following study for my research "**EFFECT OF CRYOTHERAPY ON ARTERIOVENOUS FISTULA PUNCTURE RELATED PAIN AMONG PATIENTS UNDERGOING HEMODIALYSIS AT SRI RAMAKRISHNA HOSPITAL, COIMBATORE**". The follow tool is intended to be used, hence I request you to kindly give me a valuable suggestion and necessary for the continuing the study.

Thanking you,

Coimbatore,
1.09.17

PRINCIPAL
College of Nursing
Sri Ramakrishna Institute of Paramedical Science
Coimbatore-641044

Yours sincerely,

(J. Berin sheeba)

FORMAT OF THE STUDY

Name of the expert: Dr. S. Madhavi

Address: Principal
KMCH College of Nursing,
Coimbatore - 14.

Kindly validate each tool and tick wherever applicable

S.NO	Section of the tool	Strongly agree	Agree	Need modification	Remarks
1.	Section A	✓			
2.	Section B	✓			
3.	Section C	✓			
4.	Section D	✓			

Total content of the tool: Adequate/Inadequate

Date:

Signature of the expert

The Principal
K.M.C.H. College of Nursing
P.B. No. : 3209, Avanashi Road,
Coimbatore - 641 014.

REQUISITION LETTER TO VALIDATE THE RESEARCH TOOL AND CONTENT

From,

Ms. Berin sheeba .J,

M.Sc. Nursing 1st year,

College of Nursing, SRIPMS,

Coimbatore.

To,

The Principal,

PSG College of Nursing,

Coimbatore.

Through

The Principal,

College of Nursing, SRIPMS,

Coimbatore.

Respected Sir/Madam

Subject: Requesting permission to validate the research tool and content

I am Ms. Berin sheeba. J doing my 1st year MSc Nursing in College Of Nursing, Sri Ramakrishna Institute of Paramedical Science. As a part of my Nursing program, I have undertaken the following study for my research "**EFFECT. OF CRYOTHERAPY ON ARTERIOVENOUS FISTULA PUNCTURE RELATED PAIN AMONG PATIENTS UNDERGOING HEMODIALYSIS AT SRI RAMAKRISHNA HOSPITAL, COIMBATORE**". The follow tool is intended to be used, hence I request you to kindly give me a valuable suggestion and necessary for the continuing the study.

Thanking you,

Yours sincerely,

Coimbatore,

1.09.17

(J. Berin sheeba)

To Dr. Tamilselvi

1/9/17

PRINCIPAL
College of Nursing
Sri Ramakrishna Institute of Paramedical Sciences
Coimbatore - 641 044

FORMAT OF THE STUDY

Name of the expert:

Ms. SUDHA PRIYA. S.
Asst. PROFESSOR.

Address:

PSG COLLEGE OF NURSING
PEELAMEDU
COIMBATORE – 4.

Kindly validate each tool and tick wherever applicable

S.NO	Section of the tool	Strongly agree	Agree	Need modification	Remarks
1.	Section A	✓			
2.	Section B	✓			Need of Discussion
3.	Section C	✓			
4.	Section D	✓			

Total content of the tool: Adequate/Inadequate

Date: 23.10.17

Signature of the expert

REQUISITION LETTER TO VALIDATE THE RESEARCH TOOL AND CONTENT

From,

Ms. Berin sheeba .J,

M.Sc. Nursing 1st year,

College of Nursing, SRIPMS,

Coimbatore.

To,

The Principal,
KG College of Nursing,
Coimbatore.

Through

The Principal,

College of Nursing, SRIPMS,

Coimbatore.

Respected Sir/Madam

Subject: Requesting permission to validate the research tool and content

I am Ms. Berin sheeba. J doing my 1st year MSc Nursing in College Of Nursing, Sri Ramakrishna Institute of Paramedical Science. As a part of my Nursing program, I have undertaken the following study for my research "**EFFECT OF CRYOTHERAPY ON ARTERIOVENOUS FISTULA PUNCTURE RELATED PAIN AMONG PATIENTS UNDERGOING HEMODIALYSIS AT SRI RAMAKRISHNA HOSPITAL, COIMBATORE**". The follow tool is intended to be used, hence I request you to kindly give me a valuable suggestion and necessary for the continuing the study.

Thanking you,

Coimbatore,

10.10.17

PRINCIPAL
College of Nursing
Sri Ramakrishna Institute of Paramedical Science
Coimbatore - 641 044

Yours sincerely,

(J. Berin sheeba)

FORMAT OF THE STUDY

Name of the expert: Mrs. A. SANTHI PRIYA

Address: PROFESSOR,
HOD MEDICAL SURGICAL NURSING DEPARTMENT,
K.G. COLLEGE OF NURSING,
COIMBATORE

Kindly validate each tool and tick wherever applicable

S.NO	Section of the tool	Strongly agree	Agree	Need modification	Remarks
1.	Section A			✓	
2.	Section B		✓		
3.	Section C		✓		
4.	Section D	✓			

Total content of the tool: Adequate/Inadequate ✓

Date: 24/11/2017

A. Santhi

Signature of the expert

K.G. College of Nursing, K.G. Hospital
24 NOV 2017
Coimbatore-16
College Code No: 2904009

TOOL FOR DATA COLLECTION

The tool consists of 4 components.

Section A: Demographic profile.

Section B: Physiological parameters

Section C: Modified Abbey pain scale for objective pain assessment

Section D: Numerical Pain Rating scale for subjective pain assessment.

SECTION A: DEMOGRAPHIC PROFILE

Sample no:

1. Age
   a) 31-40Years
   b) 41-50 Years
   c) 51- 60Years
   d) 61-70 Years

2. Gender
   a) Male
   b) Female

3. Education
   a) Illiterate
   b) Primary School
   c) Middle school
   d) High school
   e) Higher Secondary
   f) Graduation and Post-graduation

4. Occupation
   a) Employed
   b) Unemployed

5. Family Monthly Income
   a) Below 5000
   b) 5001 – 10,000
   c) 10,001 – 15,000
   d) Above 15,001

6. Duration of diagnosis of Renal Failure:
   a) Less than 1 year
   b) 1-10 years
   c) 11-20 years
   d) More than 20 years

7. Duration of hemodialysis
   a) Less than 1 year
   b) 1-5 years
   c) More than 5 years

8. Duration of present AV fistula
   a) 1-6 months
   b) 7-12 months
   c) 13-18 months
   d) 19-24 months

9. Do you have any other associated illness
   a) Yes
   b) No
   c) If Yes Specify……

10. Number of hemodialysis cycles per week
   a) Two
   b) Three

SECTION B: PHYSIOLOGICAL PARAMETERS

NO. OF DAYS	I Assessment		II Assessment		III Assessment		IV Assessment		V Assessment		VI Assessment	
PHYSIOLOGICAL PARAMETERS	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
PULSE RATE												
RESPIRATION												
BLOOD PRESSURE												

SECTION C: MODIFIED ABBEY PAIN SCALE FOR OBJECTIVE PAIN ASSESSMENT

SCORING	I Assessment	II Assessment	III Assessment	IV Assessment	V Assessment	VI Assessment
VOCALIZATION						
e.g.: Whimpering, groaning, crying Absent 0 Mild 1 Moderate Severe 3						
FACIAL EXPRESSION						
e.g.: Looking tense, frowning and grimacing, looking frightened Absent0 Mild 1 Moderate 2 Severe 3						
CHANGE IN BODY LANGUAGE						
e.g.: Fidgeting, rocking, guarding part of body and withdrawn Absent 0 Mild 1 Moderate 2 Severe 3						
MOOD CHANGES						
E.g.: Irritation, anger, aggressive Absent 0 Mild 1 Moderate 2 Severe 3						
TOTAL SCORE **No pain 0-3** **Mild pain 4-6** **Moderate pain 7-9** **Severe pain 10-12**						

SECTION D: NUMERICAL RATING PAIN SCALE FOR SUBJECTIVE PAIN ASSESSMENT

SCORING	I Assessment	II Assessment	III Assessment	IV Assessment	V Assessment	VI Assessment
No pain (0)						
Mild (1-3)						
Moderate (4-6)						
Severe (7-10)						

ANNEXURE I

Analysis on effect of cryotherapy on arteriovenous fistula puncture related pain among patients undergoing hemodialysis

Student 't' test was used to analysis the effect of cryotherapy on arteriovenous fistula puncture related pain using Numerical subjective pain assessment scale and Modified Abbey objective pain assessment scale among patients undergoing hemodialysis.

$$|t| = \left| \frac{\overline{X} - \overline{Y}}{S\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}} \right|$$

Where,

$\overline{X}$ = Mean Pain scores of the routine care

$\overline{Y}$ = Mean Pain scores of the cryotherapy

$$S = \sqrt{\frac{1}{n_1 + n_2 - 2}\left[\sum(x - \bar{x})^2 + \sum(y - \bar{y})^2\right]}$$

n_1 = Total number of samples in routine care

n_2 = Total number of samples in cryotherapy

ANNEXURE I -1

Analysis on the effect of cryotherapy on arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment scale in Group I Routine care and Cryotherapy

S. No	X	$X-\bar{X}$	$(X-\bar{X})^2$	Y	$Y-\bar{Y}$	$(Y-\bar{Y})^2$
1	0.5	-3.53	12.46	0.5	-1.33	1.77
2	5	0.97	0.94	2	0.17	0.03
3	1.5	-2.53	6.40	0.2	-1.63	2.66
4	5.5	1.47	2.16	2	0.17	0.03
5	4.5	0.47	0.22	1.5	-0.33	0.11
6	5.5	1.47	2.16	2.5	0.67	0.45
7	6.5	2.47	6.10	4.5	2.67	7.13
8	4.5	0.47	0.22	2	0.17	0.03
9	4	-0.03	0.00	2	0.17	0.03
10	3.5	-0.53	0.28	2	0.17	0.03
11	4	-0.03	0.00	2	0.17	0.03
12	4.5	0.47	0.22	1.5	-0.33	0.11
13	4	-0.03	0.00	1.5	-0.33	0.11
14	4.5	0.47	0.22	2	0.17	0.03
15	4	-0.03	0.00	2	0.17	0.03
16	3	-1.03	1.06	1.5	-0.33	0.11
17	4	-0.03	0.00	2	0.17	0.03
18	3.5	-0.53	0.28	1	-0.83	0.69
19	4	-0.03	0.00	2	0.17	0.03
Total	**76.5**	**-0.07**	**32.74**	**34.7**	**-0.07**	**13.42**

$$S = \sqrt{\frac{1}{n_1 + n_2 - 2}\left[\sum(x - \bar{x})^2 + \sum(y - \bar{y})^2\right]}$$

$$= \sqrt{\frac{1}{19+19-2}}[32.74 + 13.42]$$

= 1.18

$$|t| = \left| \frac{\overline{X} - \overline{Y}}{S\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}} \right|$$

Where,

$\overline{X}$ = Mean Pain scores of the routine care

$\overline{Y}$ = Mean Pain scores of the cryotherapy

$$= \left| \frac{4.03 - 1.83}{1.18\sqrt{\frac{1}{19} + \frac{1}{19}}} \right|$$

= 5.8

ANNEXURE I -2

Analysis on the effect of cryotherapy on arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment Scale in Group II Cryotherapy and Routine care

S. No	X	$X-\bar{X}$	$(X-\bar{X})^2$	Y	$Y-\bar{Y}$	$(Y-\bar{Y})^2$
1	0.5	-1.26	1.59	2	-1.82	3.31
2	2.7	0.94	0.88	6	2.18	4.75
3	2.3	0.54	0.29	3	-0.82	0.67
4	1.5	-0.26	0.07	3	-0.82	0.67
5	2.5	0.74	0.55	4	0.18	0.03
6	1.5	-0.26	0.07	4.5	0.68	0.46
7	1	-0.76	0.58	5	1.18	1.39
8	1.5	-0.26	0.07	4.5	0.68	0.46
9	2	0.24	0.06	4	0.18	0.03
10	2	0.24	0.06	4.5	0.68	0.46
11	1	-0.76	0.58	4	0.18	0.03
12	2	0.24	0.06	3	-0.82	0.67
13	2	0.24	0.06	3	-0.82	0.67
14	1.5	-0.26	0.07	4	0.18	0.03
15	1	-0.76	0.58	4	0.18	0.03
16	1.5	-0.26	0.07	3	-0.82	0.67
17	1.5	-0.26	0.07	3.5	-0.32	0.10
18	3	1.24	1.54	3.5	-0.32	0.10
19	2.5	0.74	0.55	4	0.18	0.03
Total	**33.5**	**0.06**	**7.76**	**72.5**	**-0.08**	**14.61**

$$S = \sqrt{\frac{1}{n_1 + n_2 - 2}\left[\sum(x - \bar{x})^2 + \sum(y - \bar{y})^2\right]}$$

$$= \sqrt{\frac{1}{19+19-2}}[7.76 + 14.61]$$

$$= \mathbf{0.82}$$

$$|t| = \left| \frac{\overline{X} - \overline{Y}}{S\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}} \right|$$

Where,

$\overline{X}$ = Mean Pain scores of the cryotherapy

$\overline{Y}$ = Mean Pain scores of the routine care

$$= \left| \frac{1.76 - 3.82}{0.82\sqrt{\frac{1}{19} + \frac{1}{19}}} \right|$$

$$= \mathbf{7.9}$$

ANNEXURE I -3

Analysis on the effect of cryotherapy on arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment scale in Group I and II Routine care

S. No	X	$X-\bar{X}$	$(X-\bar{X})^2$	Y	$Y-\bar{Y}$	$(Y-\bar{Y})^2$
1	0.5	-3.53	12.46	2	-1.82	3.31
2	5	0.97	0.94	6	2.18	4.75
3	1.5	-2.53	6.40	3	-0.82	0.67
4	5.5	1.47	2.16	3	-0.82	0.67
5	4.5	0.47	0.22	4	0.18	0.03
6	5.5	1.47	2.16	4.5	0.68	0.46
7	6.5	2.47	6.10	5	1.18	1.39
8	4.5	0.47	0.22	4.5	0.68	0.46
9	4	-0.03	0.00	4	0.18	0.03
10	3.5	-0.53	0.28	4.5	0.68	0.46
11	4	-0.03	0.00	4	0.18	0.03
12	4.5	0.47	0.22	3	-0.82	0.67
13	4	-0.03	0.00	3	-0.82	0.67
14	4.5	0.47	0.22	4	0.18	0.03
15	4	-0.03	0.00	4	0.18	0.03
16	3	-1.03	1.06	3	-0.82	0.67
17	4	-0.03	0.00	3.5	-0.32	0.10
18	3.5	-0.53	0.28	3.5	-0.32	0.10
19	4	-0.03	0.00	4	0.18	0.03
Total	**76.5**	**-0.07**	**32.74**	**72.5**	**-0.08**	**14.61**

$$S = \sqrt{\frac{1}{n_1+n_2-2}\left[\sum(x-\bar{x})^2+\sum(y-\bar{y})^2\right]}$$

$$= \sqrt{\frac{1}{19+19-2}}[32.74+14.61]$$

= 1.2

$$|t| = \left|\frac{\overline{X}-\overline{Y}}{S\sqrt{\frac{1}{n_1}+\frac{1}{n_2}}}\right|$$

Where,

$\bar{x}$ = Mean Pain scores of the Group I routine care

$\overline{Y}$ = Mean Pain scores of the Group II routine care

$$= \left|\frac{4.03-3.82}{1.2\sqrt{\frac{1}{19}+\frac{1}{19}}}\right|$$

= 0.55

ANNEXURE I -4

Analysis on the effect of cryotherapy on arteriovenous fistula puncture related pain using Modified Abbey objective pain assessment scale in Group I and II Cryotherapy

S. No	X	$X-\bar{X}$	$(X-\bar{X})^2$	Y	$Y-\bar{Y}$	$(Y-\bar{Y})^2$
1	0.5	-1.33	1.77	0.5	-1.26	1.59
2	2	0.17	0.03	2.7	0.94	0.88
3	0.2	-1.63	2.66	2.3	0.54	0.29
4	2	0.17	0.03	1.5	-0.26	0.07
5	1.5	-0.33	0.11	2.5	0.74	0.55
6	2.5	0.67	0.45	1.5	-0.26	0.07
7	4.5	2.67	7.13	1	-0.76	0.58
8	2	0.17	0.03	1.5	-0.26	0.07
9	2	0.17	0.03	2	0.24	0.06
10	2	0.17	0.03	2	0.24	0.06
11	2	0.17	0.03	1	-0.76	0.58
12	1.5	-0.33	0.11	2	0.24	0.06
13	1.5	-0.33	0.11	2	0.24	0.06
14	2	0.17	0.03	1.5	-0.26	0.07
15	2	0.17	0.03	1	-0.76	0.58
16	1.5	-0.33	0.11	1.5	-0.26	0.07
17	2	0.17	0.03	1.5	-0.26	0.07
18	1	-0.83	0.69	3	1.24	1.54
19	2	0.17	0.03	2.5	0.74	0.55
Total	**34.7**	**-0.07**	**13.42**	**33.5**	**0.06**	**7.76**

$$S = \sqrt{\frac{1}{n_1 + n_2 - 2}\left[\sum(x - \bar{x})^2 + \sum(y - \bar{y})^2\right]}$$

$$= \sqrt{\frac{1}{19+19-2}}[13.42 + 7.76]$$

= 0.8

$$|t| = \left| \frac{\overline{X} - \overline{Y}}{S\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}} \right|$$

Where,

$\bar{x}$ = Mean Pain scores of the Group I cryotherapy

$\overline{Y}$ = Mean Pain scores of the Group II cryotherapy

$$= \left| \frac{1.83 - 1.76}{0.8\sqrt{\frac{1}{19} + \frac{1}{19}}} \right|$$

= 0.27

ANNEXURE I - 5

Analysis on the effect of cryotherapy on arteriovenous fistula puncture related pain using Numerical subjective pain assessment Rating scale in Group I Routine care and Cryotherapy

S. No	X	$X-\bar{X}$	$(X-\bar{X})^2$	Y	$Y-\bar{Y}$	$(Y-\bar{Y})^2$
1	3	-3.07	9.42	0	-2.04	4.16
2	6.7	0.63	0.40	2.7	0.66	0.44
3	3.5	-2.57	6.60	0	-2.04	4.16
4	6.5	0.43	0.18	3.5	1.46	2.13
5	6.5	0.43	0.18	2.5	0.46	0.21
6	9.5	3.43	11.76	3	0.96	0.92
7	10	3.93	15.44	7	4.96	24.60
8	5.5	-0.57	0.32	0.5	-1.54	2.37
9	5.5	-0.57	0.32	1.5	-0.54	0.29
10	5	-1.07	1.14	1	-1.04	1.08
11	6.5	0.43	0.18	2.5	0.46	0.21
12	5.5	-0.57	0.32	1	-1.04	1.08
13	6.5	0.43	0.18	2	-0.04	0.00
14	5.5	-0.57	0.32	2.5	0.46	0.21
15	7.5	1.43	2.04	3.5	1.46	2.13
16	6	-0.07	0.00	1	-1.04	1.08
17	6.7	0.63	0.40	2	-0.04	0.00
18	3	-3.07	9.42	0.5	-1.54	2.37
19	6.5	0.43	0.18	2	-0.04	0.00
Total	**115.4**	**0.07**	**58.88**	**38.7**	**-0.06**	**47.46**

$$S = \sqrt{\frac{1}{n_1 + n_2 - 2}\left[\sum(x - \bar{x})^2 + \sum(y - \bar{y})^2\right]}$$

$$= \sqrt{\frac{1}{19+19-2}}[58.88 + 47.46]$$

$$= \mathbf{1.8}$$

$$|t| = \left| \frac{\overline{X} - \overline{Y}}{S\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}} \right|$$

Where,

$\overline{X}$ = Mean Pain scores of the routine care

$\overline{Y}$ = Mean Pain scores of the cryotherapy

$$= \left| \frac{6.07 - 2.04}{1.8\sqrt{\frac{1}{19} + \frac{1}{19}}} \right|$$

$$= \mathbf{6.95}$$

ANNEXURE I - 6

Analysis on the effect of cryotherapy on arteriovenous fistula puncture related pain using Numerical subjective pain assessment Rating scale in Group II Cryotherapy and Routine care

S. No	X	$X-\bar{X}$	$(X-\bar{X})^2$	Y	$Y-\bar{Y}$	$(Y-\bar{Y})^2$
1	1.5	-0.58	0.34	5.5	-0.5	0.25
2	2.7	0.62	0.38	6.7	0.7	0.49
3	3.7	1.62	2.62	8	2	4
4	2.5	0.42	0.18	6	0	0
5	3.5	1.42	2.02	6.5	0.5	0.25
6	4	1.92	3.69	6.5	0.5	0.25
7	3	0.92	0.85	7.5	1.5	2.25
8	1.5	-0.58	0.34	5	-1	1
9	1	-1.08	1.17	6.5	0.5	0.25
10	1.5	-0.58	0.34	5.5	-0.5	0.25
11	1.7	-0.38	0.14	6.3	0.3	0.09
12	1.5	-0.58	0.34	5.5	-0.5	0.25
13	1.5	-0.58	0.34	5.5	-0.5	0.25
14	1	-1.08	1.17	4.5	-1.5	2.25
15	2.5	0.42	0.18	6.5	0.5	0.25
16	2	-0.08	0.01	4	-2	4
17	1.5	-0.58	0.34	5.5	-0.5	0.25
18	1.5	-0.58	0.34	6.5	0.5	0.25
19	1.5	-0.58	0.34	5.5	-0.5	0.25
Total	**39.6**	**0.08**	**15.09**	**113.5**	**-0.5**	**16.83**

$$S = \sqrt{\frac{1}{n_1 + n_2 - 2}\left[\sum(x - \bar{x})^2 + \sum(y - \bar{y})^2\right]}$$

$$= \sqrt{\frac{1}{19+19-2}}[15.09 + 16.83]$$

$$= \mathbf{0.98}$$

$$|t| = \left| \frac{\overline{X} - \overline{Y}}{S\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}} \right|$$

Where,

$\overline{X}$ = Mean Pain scores of the cryotherapy

$\overline{Y}$ = Mean Pain scores of the routine care

$$= \left| \frac{2.08 - 6}{0.98\sqrt{\frac{1}{19} + \frac{1}{19}}} \right|$$

$$= \mathbf{12.65}$$

ANNEXURE I - 7

Analysis on the effect of cryotherapy on arteriovenous fistula puncture related pain using Numerical subjective pain assessment Rating Scale in Group I and II Routine care

S. No	X	$X-\bar{X}$	$(X-\bar{X})^2$	Y	$Y-\bar{Y}$	$(Y-\bar{Y})^2$
1	3	-3.07	9.42	5.5	-0.5	0.25
2	6.7	0.63	0.40	6.7	0.7	0.49
3	3.5	-2.57	6.60	8	2	4
4	6.5	0.43	0.18	6	0	0
5	6.5	0.43	0.18	6.5	0.5	0.25
6	9.5	3.43	11.76	6.5	0.5	0.25
7	10	3.93	15.44	7.5	1.5	2.25
8	5.5	-0.57	0.32	5	-1	1
9	5.5	-0.57	0.32	6.5	0.5	0.25
10	5	-1.07	1.14	5.5	-0.5	0.25
11	6.5	0.43	0.18	6.3	0.3	0.09
12	5.5	-0.57	0.32	5.5	-0.5	0.25
13	6.5	0.43	0.18	5.5	-0.5	0.25
14	5.5	-0.57	0.32	4.5	-1.5	2.25
15	7.5	1.43	2.04	6.5	0.5	0.25
16	6	-0.07	0.00	4	-2	4
17	6.7	0.63	0.40	5.5	-0.5	0.25
18	3	-3.07	9.42	6.5	0.5	0.25
19	6.5	0.43	0.18	5.5	-0.5	0.25
Total	**115.4**	**0.07**	**58.88**	**113.5**	**-0.5**	**16.83**

$$S = \sqrt{\frac{1}{n_1+n_2-2}\left[\sum(x-\bar{x})^2+\sum(y-\bar{y})^2\right]}$$

$$= \sqrt{\frac{1}{19+19-2}}[58.88 + 16.83]$$

$$= \mathbf{1.5}$$

$$|t| = \left|\frac{\overline{X}-\overline{Y}}{S\sqrt{\frac{1}{n_1}+\frac{1}{n_2}}}\right|$$

Where,

$\overline{X}$ = Mean Pain scores of the group I routine care

$\overline{Y}$ = Mean Pain scores of the group II routine care

$$= \left|\frac{6.07-6}{1.5\sqrt{\frac{1}{19}+\frac{1}{19}}}\right|$$

$$= \mathbf{1.5}$$

ANNEXURE I - 8

Analysis on the effect of cryotherapy on arteriovenous fistula puncture related pain using Numerical subjective pain assessment Rating Scale in Group I and II Cryotherapy

S. No	X	$X-\bar{X}$	$(X-\bar{X})^2$	Y	$Y-\bar{Y}$	$(Y-\bar{Y})^2$
1	0	-2.04	4.16	1.5	-0.58	0.34
2	2.7	0.66	0.44	2.7	0.62	0.38
3	0	-2.04	4.16	3.7	1.62	2.62
4	3.5	1.46	2.13	2.5	0.42	0.18
5	2.5	0.46	0.21	3.5	1.42	2.02
6	3	0.96	0.92	4	1.92	3.69
7	7	4.96	24.60	3	0.92	0.85
8	0.5	-1.54	2.37	1.5	-0.58	0.34
9	1.5	-0.54	0.29	1	-1.08	1.17
10	1	-1.04	1.08	1.5	-0.58	0.34
11	2.5	0.46	0.21	1.7	-0.38	0.14
12	1	-1.04	1.08	1.5	-0.58	0.34
13	2	-0.04	0.00	1.5	-0.58	0.34
14	2.5	0.46	0.21	1	-1.08	1.17
15	3.5	1.46	2.13	2.5	0.42	0.18
16	1	-1.04	1.08	2	-0.08	0.01
17	2	-0.04	0.00	1.5	-0.58	0.34
18	0.5	-1.54	2.37	1.5	-0.58	0.34
19	2	-0.04	0.00	1.5	-0.58	0.34
Total	**38.7**	**-0.06**	**47.46**	**39.6**	**0.08**	**15.09**

$$S = \sqrt{\frac{1}{n_1+n_2-2}\left[\sum(x-\bar{x})^2+\sum(y-\bar{y})^2\right]}$$

$$= \sqrt{\frac{1}{19+19-2}}[47.46 + 15.09]$$

= 1.37

$$|t| = \left|\frac{\overline{X}-\overline{Y}}{S\sqrt{\frac{1}{n_1}+\frac{1}{n_2}}}\right|$$

Where,

$\overline{X}$ = Mean Pain scores of the group I Cryotherapy

$\overline{Y}$ = Mean Pain scores of the group II Cryotherapy

$$= \left|\frac{2.04-2.08}{1.37\sqrt{\frac{1}{19}+\frac{1}{19}}}\right|$$

= 0.09

ANNEXURE II

Correlation between the arteriovenous fistula puncture related pain observed using Modified Abbey pain scale and Numerical Pain Rating scale

Karl Pearson's Coefficient Correlation was used to correlate the level of arteriovenous fistula puncture related pain observed using Modified Abbey pain scale and Numerical Pain Rating scale among patient undergoing hemodialysis.

$$\mathbf{r} = \frac{\sum(X-\overline{X})(Y-\overline{Y})}{\sqrt{\sum(X-\overline{X})^2 \sum(Y-\overline{Y})^2}}$$

$\overline{X}$ = mean pain observed using modified Abbey pain scale scores.

$\overline{Y}$ = mean pain observed using numerical pain rating scale scores.

ANNEXURE II - 1

Correlation between the arteriovenous fistula puncture related pain observed using Modified Abbey pain scale and Numerical Pain Rating scale among Group I and II cryotherapy

S. No	X	$X - \bar{X}$	$(X - \bar{X})^2$	y	$Y-\bar{Y}$	$(Y-\bar{Y})^2$	$(X - \bar{X})(Y-\bar{Y})$
1	0	-2.06	4.24	0.5	-1.3	1.69	2.68
2	1.5	-0.56	0.31	0.5	-1.3	1.69	0.73
3	2.7	0.64	0.41	2	0.2	0.04	0.13
4	2.7	0.64	0.41	2.7	0.9	0.81	0.58
5	0	-2.06	4.24	0.2	-1.6	2.56	3.30
6	3.7	1.64	2.69	2.3	0.5	0.25	0.82
7	3.5	1.44	2.07	2	0.2	0.04	0.29
8	2.5	0.44	0.19	1.5	-0.3	0.09	-0.13
9	2.5	0.44	0.19	1.5	-0.3	0.09	-0.13
10	3.5	1.44	2.07	2.5	0.7	0.49	1.01
11	3	0.94	0.88	2.5	0.7	0.49	0.66
12	4	1.94	3.76	1.5	-0.3	0.09	-0.58
13	7	4.94	24.40	4.5	2.7	7.29	13.34
14	3	0.94	0.88	1	-0.8	0.64	-0.75
15	0.5	-1.56	2.43	2	0.2	0.04	-0.31
16	1.5	-0.56	0.31	1.5	-0.3	0.09	0.17
17	1.5	-0.56	0.31	2	0.2	0.04	-0.11
18	1	-1.06	1.12	2	0.2	0.04	-0.21
19	1	-1.06	1.12	2	0.2	0.04	-0.21
20	1.5	-0.56	0.31	2	0.2	0.04	-0.11
21	2.5	0.44	0.19	2	0.2	0.04	0.09
22	1.7	-0.36	0.13	1	-0.8	0.64	0.29
23	1	-1.06	1.12	1.5	-0.3	0.09	0.32
24	1.5	-0.56	0.31	2	0.2	0.04	-0.11
25	2	-0.06	0.00	1.5	-0.3	0.09	0.02
26	1.5	-0.56	0.31	2	0.2	0.04	-0.11
27	2.5	0.44	0.19	2	0.2	0.04	0.09
28	1	-1.06	1.12	1.5	-0.3	0.09	0.32
29	3.5	1.44	2.07	2	0.2	0.04	0.29
30	2.5	0.44	0.19	1	-0.8	0.64	-0.35
31	1	-1.06	1.12	1.5	-0.3	0.09	0.32
32	2	-0.06	0.00	1.5	-0.3	0.09	0.02
33	2	-0.06	0.00	2	0.2	0.04	-0.01
34	1.5	-0.56	0.31	1.5	-0.3	0.09	0.17
35	0.5	-1.56	2.43	1	-0.8	0.64	1.25
36	1.5	-0.56	0.31	3	1.2	1.44	-0.67
37	2	-0.06	0.00	2	0.2	0.04	-0.01
38	1.5	-0.56	0.31	2.5	0.7	0.49	-0.39
Total	**78.3**	**0.02**	**62.57**	**68.2**	**-0.2**	**21.22**	**22.62**

$$\mathbf{r} = \frac{\sum(X-\overline{X})(Y-\overline{Y})}{\sqrt{\sum(X-\overline{X})^2 \sum(Y-\overline{Y})^2}}$$

$$= \frac{(22.62)}{\sqrt{(62.57)(21.22)}}$$

r = 0.6

ANNEXURE II - 2

Correlation between the arteriovenous fistula puncture related pain observed using Modified Abbey pain scale and Numerical Pain Rating scale among Group I and II Routine care

S. No	X	$X - \bar{X}$	$(X - \bar{X})^2$	Y	$Y-\bar{Y}$	$(Y-\bar{Y})^2$	$(X - \bar{X})(Y-\bar{Y})$
1	3	-3.02	9.12	0.5	-3.4	11.56	10.27
2	5.5	-0.52	0.27	2	-1.9	3.61	0.99
3	6.7	0.68	0.46	5	1.1	1.21	0.75
4	6.7	0.68	0.46	6	2.1	4.41	1.43
5	3.5	-2.52	6.35	1.5	-2.4	5.76	6.05
6	8	1.98	3.92	3	-0.9	0.81	-1.78
7	6.5	0.48	0.23	5.5	1.6	2.56	0.77
8	6	-0.02	0.00	3	-0.9	0.81	0.02
9	6.5	0.48	0.23	4.5	0.6	0.36	0.29
10	6.5	0.48	0.23	4	0.1	0.01	0.05
11	9.5	3.48	12.11	5.5	1.6	2.56	5.57
12	6.5	0.48	0.23	4.5	0.6	0.36	0.29
13	10	3.98	15.84	6.5	2.6	6.76	10.35
14	7.5	1.48	2.19	5	1.1	1.21	1.63
15	5.5	-0.52	0.27	4.5	0.6	0.36	-0.31
16	5	-1.02	1.04	4.5	0.6	0.36	-0.61
17	5.5	-0.52	0.27	4	0.1	0.01	-0.05
18	6.5	0.48	0.23	4	0.1	0.01	0.05
19	5	-1.02	1.04	3.5	-0.4	0.16	0.41
20	5.5	-0.52	0.27	4.5	0.6	0.36	-0.31
21	6.5	0.48	0.23	4	0.1	0.01	0.05
22	6.3	0.28	0.08	4	0.1	0.01	0.03
23	5.5	-0.52	0.27	4.5	0.6	0.36	-0.31
24	5.5	-0.52	0.27	3	-0.9	0.81	0.47
25	6.5	0.48	0.23	4	0.1	0.01	0.05
26	5.5	-0.52	0.27	3	-0.9	0.81	0.47
27	5.5	-0.52	0.27	4.5	0.6	0.36	-0.31
28	4.5	-1.52	2.31	4	0.1	0.01	-0.15
29	7.5	1.48	2.19	4	0.1	0.01	0.15
30	6.5	0.48	0.23	4	0.1	0.01	0.05
31	6	-0.02	0.00	3	-0.9	0.81	0.02
32	4	-2.02	4.08	3	-0.9	0.81	1.82
33	6.7	0.68	0.46	4	0.1	0.01	0.07
34	5.5	-0.52	0.27	3.5	-0.4	0.16	0.21
35	3	-3.02	9.12	3.5	-0.4	0.16	1.21
36	6.5	0.48	0.23	3.5	-0.4	0.16	-0.19
37	6.5	0.48	0.23	4	0.1	0.01	0.05
38	5.5	-0.52	0.27	4	0.1	0.01	-0.05
Total	**228.9**	**0.14**	**75.79**	**149**	**0.8**	**47.78**	**39.42**

$$\mathbf{r} = \frac{\sum(X-\overline{X})(Y-\overline{Y})}{\sqrt{\sum(X-\overline{X})^2 \sum(Y-\overline{Y})^2}}$$

$$= \frac{(39.42)}{\sqrt{(75.79)(47.78)}}$$

r = 0.7